Placement of Acticon artificial bowel sphincters in the management of faecal incontinence

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Assessment report

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The Medical Services Advisory Committee (MSAC) is an independent committee which has been established to provide advice to the Minister for Health and Ageing on the strength of evidence available on new and existing medical technologies and procedures in terms of their safety, effectiveness and cost-effectiveness. This advice will help to inform government decisions about which medical services should attract funding under Medicare.

MSAC recommendations do not necessarily reflect the views of all individuals who participated in the MSAC evaluation.

This report was prepared by the Medical Services Advisory Committee with the assistance of Ms Liz Buckley, Ms Tracy Merlin and Professor Janet Hiller from Adelaide Health Technology Assessment. The report was edited by Ms Jo Mason, MasonEdit, Adelaide. This recommendation was endorsed by the Minister for Health and Ageing on 11 April 2008.

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Executive summary

The procedure

Faecal continence is defined as 'the ability to store faeces until a socially acceptable time and to void under conscious control'. Faecal *incontinence* is a distressing and socially disabling chronic condition in which patients often suffer from embarrassment, shame and sometimes depression. The Acticon artificial bowel sphincter (ABS) is a device that aims to restore faecal continence to affected individuals.

Implantation of the Acticon ABS involves the placement of three components – an inflatable cuff a pressure-regulating balloon and a control pump – while the patient is under general anaesthesia. The inflatable cuff, which is available in varying lengths and widths, is placed around the anus and acts as an artificial sphincter. The cuff is connected to the control pump, which is placed in the scrotum of males and in the labia of females. Tubing connects the control pump to the pressure-regulating balloon, which is placed in the prevesical space, via a separate incision in the lower abdomen, and filled with radiopaque fluid.

When the system is activated after surgery (approximately 6 weeks), fluid fills the cuff, subsequently closing off the anal canal and providing continence. To defecate, the patient manually manipulates the control pump, causing the fluid to drain from the cuff into the pressure-regulating balloon. This deflates the cuff, opens the anal canal and allows defecation to proceed. The fluid gradually fills back into the cuff after 7–10 minutes, restoring continence.

Medical Services Advisory Committee – role and approach

The Medical Services Advisory Committee (MSAC) was established by the Australian Government to strengthen the role of evidence in health financing decisions in Australia. The MSAC advises the Minister for Health and Ageing on the evidence relating to the safety, effectiveness and cost-effectiveness of new and existing medical technologies and procedures, and under what circumstances public funding should be supported.

A rigorous assessment of evidence is thus the basis of decision-making when funding is sought under Medicare. A team from Adelaide Health Technology Assessment, Discipline of Public Health, School of Population Health and Clinical Practice, University of Adelaide, was engaged to conduct a systematic review of literature on implantation of the Acticon ABS in the management of faecal incontinence. The comparators which were considered in this assessment were dynamic graciloplasty, conservative management of severe faecal incontinence and colostomy. An advisory panel with expertise in this area then evaluated the evidence and provided advice to the MSAC.

MSAC's assessment of artificial bowel sphincters in the management of faecal incontinence

Clinical need

The prevalence of faecal incontinence within the general Australian population is reported to range between 3 per cent and 16 per cent. Data regarding the prevalence of *severe* faecal incontinence in Australia are not available.

Expert opinion suggests that the prevalence of solid faecal incontinence (2%) reported in one included study would be representative of the prevalence of *severe* faecal incontinence in the adult Australian population. Of these people with severe faecal incontinence, it is anticipated that less than half would be suitable for implantation of the Acticon ABS.

Due to the variation in definitions of faecal incontinence, and that the populations considered in the body of evidence do not reflect those suitable for this procedure, prevalence of severe faecal incontinence is not considered a reliable measure of clinical need. Alternatively, current surgical practice indicates that an average of four dynamic graciloplasty procedures are performed annually in Australia, and expert opinion suggests this would be a more reliable estimate of clinical need for the Acticon ABS. The inconsistency between clinical need and expected uptake of the procedure is considered to be due to a number of factors including:

- patients not readily seeking treatment
- poor identification and investigation of faecal incontinence resulting in many patients not being aware of treatment options
- patient preference regarding treatment options.

Safety

Twenty-one studies reported complications associated with implantation of the Acticon ABS. Three of these were comparative studies which compared the Acticon ABS to either conservative management or dynamic graciloplasty.

No data were identified which compared implantation of the Acticon ABS with a colostomy procedure.

Implantation of the Acticon ABS is associated with a high rate of significant complications. The range of adverse event rates were: infection (0–46%), erosion (0–43%), removal of device (0–51%), problematic pain (0–33%) and surgical revision (0–49%). No studies reported on patients once the device had been removed; therefore, it is not possible to determine if further complications arose or if there were complications subsequent to the removal procedure. It is evident from the published studies that complications were not limited to the immediate post-operative period; in particular, infection and erosion may occur some time after the initial placement of the device.

Limited evidence of the comparative safety of the Acticon ABS versus conservative management suggests that the Acticon ABS is not as safe as conservative management. It would also appear that the Acticon ABS is likely to be at least as safe as dynamic

graciloplasty, with the caution that the latter procedure is also associated with high rates of significant complications.

Effectiveness

Nineteen studies reported effectiveness outcomes associated with implantation of the Acticon ABS. Three of these were comparative studies which compared the Acticon ABS to either conservative management or dynamic graciloplasty.

No evidence was identified which compared implantation of the Acticon ABS with colostomy.

Implantation of the Acticon ABS was shown to improve faecal continence by between 27 per cent and 95 per cent in people who retained the device. No data were available regarding the change in incontinence severity for those patients for whom the device was removed. Improvements of between 44 per cent and 70 per cent in quality of life following Acticon ABS implantation were also reported.

Limited evidence indicates that implantation of the Acticon ABS is more effective than both conservative management and dynamic graciloplasty in reducing incontinence severity and improving quality of life for those people for whom the device is not removed.

Economic considerations

The improved effectiveness of the Acticon ABS compared to both conservative management and dynamic graciloplasty suggests that a formal cost-effectiveness economic evaluation is merited. However, the lack of appropriate incremental effectiveness data has prevented such an evaluation being conducted for this assessment. As a consequence, a cost comparison of the procedures has been performed.

Estimated total costs for each Acticon ABS procedure, dynamic graciloplasty, colostomy and conservative therapy are $21,163, $23,127, $8,029 and $984, respectively. The substantially higher cost associated with Acticon ABS and dynamic graciloplasty are primarily due to the cost of the devices and equipment required for the procedures.

A comparison of the expenditures associated with implantation of the Acticon ABS and its comparators indicates that the cost to the Australian government (in terms of MBS reimbursement per procedure) is similar for the Acticon ABS ($2,169), dynamic graciloplasty ($2,384) and colostomy ($2,286). Provision of conservative therapy is associated with a cost to the Australian government which is approximately one-third ($746) of the cost of the surgical interventions. It should be noted that, in this analysis, only one out of every four procedures is assumed to be performed in the private sector annually, compared to three procedures in the public sector.

Total annual cost to the Australian healthcare system for four procedures involving implantation of the Acticon ABS is estimated to be $65,658. This compares to costs of $71,765, $26,373 and $3,698 for the equivalent number of procedures for dynamic graciloplasty, colostomy and conservative therapy, respectively. In estimating these expenditures, the costs associated with related complications such as surgical revision or explantation of the Acticon ABS or dynamic graciloplasty have not been incorporated.

Recommendation

MSAC has considered the safety, effectiveness and cost-effectiveness for implantation of the Acticon artificial bowel sphincter (ABS) compared with conservative management, colostomy and dynamic graciloplasty.

MSAC finds that there is no evidence comparing the Acticon ABS with colostomy and limited evidence comparing it with conservative management and dynamic graciloplasty.

MSAC finds that the evidence suggests that Acticon ABS implantation is not as safe as conservative management and that it is likely to be at least as safe as dynamic graciloplasty.

MSAC finds that the evidence indicates that the Acticon ABS is more clinically effective than both conservative management and dynamic graciloplasty.

MSAC finds that relative cost effectiveness of the Acticon ABS and the comparators could not be assessed due to lack of data. The comparison of the estimated total costs indicates that the cost to the health system for the Acticon ABS is less than for dynamic graciloplasty.

MSAC recommends that public funding is supported for this procedure.

The Minister for Health and Ageing endorsed this recommendation on 11th April 2008.

Introduction

The Medical Services Advisory Committee (MSAC) has reviewed the use of the Acticon artificial bowel sphincter (ABS), which is a therapeutic device for the management of faecal incontinence. The MSAC evaluates new and existing health technologies and procedures for which funding is sought under the Medicare Benefits Scheme in terms of their safety, effectiveness and cost-effectiveness, while taking into account other issues such as access and equity. The MSAC adopts an evidence-based approach to its assessments, based on reviews of the scientific literature and other information sources, including clinical expertise.

The MSAC's terms of reference and membership are at Appendix A. The MSAC is a multidisciplinary expert body, comprising members drawn from such disciplines as diagnostic imaging, pathology, surgery, internal medicine and general practice, clinical epidemiology, health economics, consumer health and health administration.

This report summarises the assessment of current evidence for the placement of the Acticon ABS in the management of severe faecal incontinence.

Rationale for assessment

This assessment was undertaken as a consequence of an application from American Medical Systems Inc. to have Acticon ABS implantation publicly funded on the Medicare Benefits Schedule. Two previous applications have been submitted, by the same applicant, to the MSAC in 1999 and 2002; they were rejected on the basis of insufficient evidence pertaining to the safety, effectiveness and cost-effectiveness of this technology (MSAC 1999; MSAC 2002).

Background

Faecal continence is defined as 'the ability to store faeces until a socially acceptable time and to void under conscious control' (Cheetham et al 2001). Faecal continence is maintained through the coordinated activities of the anal sphincters (internal and external) and rectum. Disturbances to the functional and structural integrity of the anorectal unit result in faecal incontinence (Rao 2004). Reflex and voluntary control of the internal and external anal sphincters, the puborectalis sling, rectal capacitance and sensitivity all contribute to continence (Maslekar et al 2006).

There are many underlying causes of faecal incontinence (Table 1); they can be classified into anatomical, congenital, neurological or functional pathologies. Faecal incontinence is often a result of more than one abnormality (Rao 2004).The most common cause, which is related to anal sphincter damage, is obstetric trauma (Rao 2004). Many other cases result from iatrogenic damage such as anal fistula caused during surgical procedures. Congenital conditions such as Hirschsprung's disease are associated with a poorly functioning colon and faecal incontinence may occur when this condition is corrected surgically (Kamm 1998). In the aged, denervation and muscular atrophy of the pelvic floor muscles result in reduced anal canal pressures and decreased rectal compliance, resulting in faecal impaction (Jorge & Wexner 1993).

Table 1 Aetiologies of faecal incontinence

Pseudoincontinence	Urgency
Perineal soiling:	Non-compliant rectum:
Rectal mucosal prolapse	Irradiation
Haemorrhoidal prolapse	IBD[a]
Incomplete defecation	Absent rectal reservoir
Poor hygiene	IBS[b]
Dermatologic condition	
Anorectal sexually transmitted disease	
Anorectal neoplasm	
Overflow incontinence	
Impaction	Psychotropic drugs
Encopresis	Rectal neoplasms
Antimotility drugs	
Incontinence with normal pelvic floor function	
Diarrhoeal states	Systemic disease processes:
Inflammatory bowel disease:	Central nervous/spinal cord disorders
Short gut	Neoplasm
Laxative abuse	Injury
Infection	Dementia/stroke
Parasites	Multiple sclerosis
Bacteria	Scleroderma
Toxins	Neuropathies (diabetic)
Intermittent partial small bowel obstruction	
Incontinence with abnormal pelvic floor function	
Sphincter injury:	Pelvic floor denervation
Obstetric	Pudendal nerve neuropathy
Traumatic	Perineal descent syndrome
Iatrogenic	
Neoplastic	
Rectal prolapse	
Congenital abnormalities:	Traumatic
Spina bifida	Neoplastic infiltration
Imperforate anus	

Source: Oliveira & Wexner 1998; [a] inflammatory bowel disease; [b] irritable bowel syndrome

There are two types of faecal incontinence, passive and urgent. Passive faecal incontinence, where patients are not aware of faecal loss, is associated with dysfunction of the smooth muscle tissue of the internal anal sphincter or as a consequence of impacted faeces in the rectum. Conversely, patients experiencing faecal urgency are unable to postpone defecation until a socially acceptable time. This is associated with muscular dysfunction of the external sphincter or with high bowel pressure that cannot be opposed by external sphincter pressure (Kamm 1998; Malouf et al 2001). Varying degrees of both passive and urgency incontinence are seen in most patients who suffer from faecal incontinence.

Faecal incontinence is a distressing and socially disabling chronic condition in which patients often suffer from embarrassment, shame and sometimes depression (Maslekar et al 2006; Pretlove et al 2006). The stigma associated with faecal incontinence often

sees patients unwilling to discuss it, and many doctors reluctant to enquire about the condition (Madoff et al 1992).

A number of different scoring systems are available to assess the severity of symptoms of faecal incontinence. However, only one system (Table 2) considers the impact of symptom severity on quality of life (Kouraklis & Andromanakos 2004). Patients indicated for implantation with an Acticon ABS would usually score ≥ 18 using this scoring system (Vaizey et al 1998).

Table 2 Cleveland incontinence scoring system

Type of incontinence	Never	Rarely (<1/month)	Sometimes (<1/week)	Usually (<1/day)	Always (>1/day)
Solid	0	1	2	3	4
Liquid	0	1	2	3	4
Gas	0	1	2	3	4
Requires pad	0	1	2	3	4
Lifestyle alteration	0	1	2	3	4

Source: Jorge & Wexner 1993
0 points = complete continence; 20 points = complete incontinence

The procedure

The successful use of an artificial sphincter for the treatment of faecal incontinence was first reported by Christiansen et al in 1987. Early reports of the use of an artificial urinary sphincter, the AMS800 (American Medical Systems), to treat severe faecal incontinence were associated with significant infection rates and revisions (Parker et al 2003). After adjustments to overcome technical problems, the modified artificial bowel sphincter (ABS) was introduced in 1996 by American Medical Systems as the Acticon® Neosphincter.

The device comprises three components (Figure 1): an inflatable cuff, a pressure-regulating balloon and a control pump, and is constructed of solid silicone elastomere (Gregorcyk 2005). The cuff is available in two widths (2 cm or 2.9 cm) and in six lengths ranging between 9 cm and 14 cm (Parker et al 2003). Implantation of the device is performed under general anaesthesia with patients in the modified lithotomy position (Wong et al 1996).

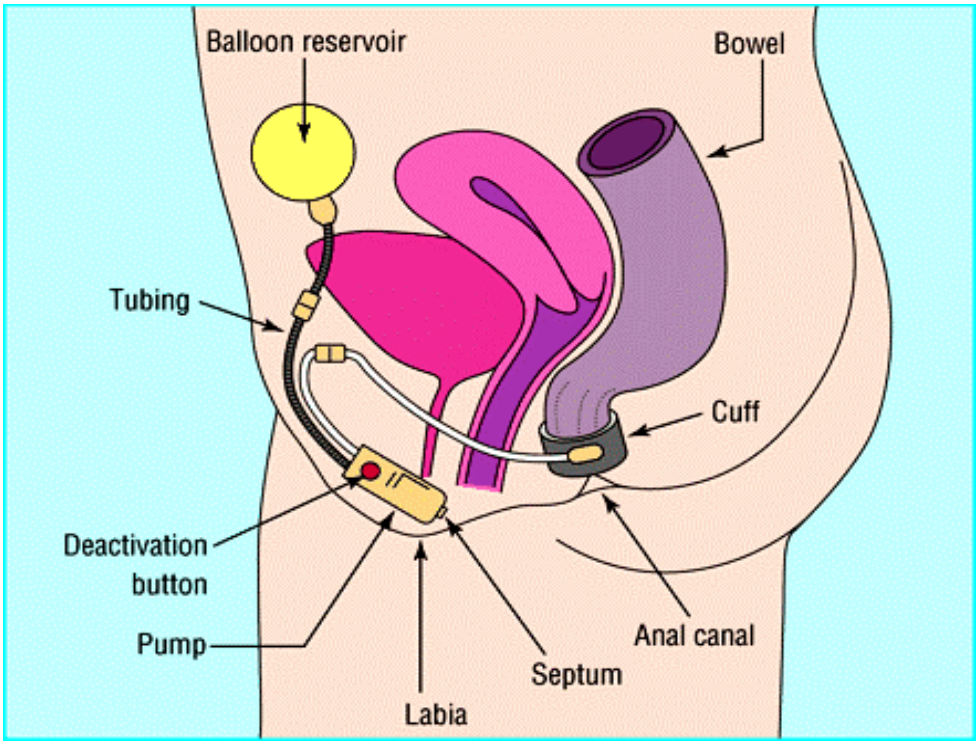
The cuff is placed around the anus and connected to the control pump, which is implanted in the scrotum for males and the labia for females (Wong et al 1996). The pressure-regulating balloon is implanted in the prevesical space via a lower abdominal incision, and is connected to the control pump via tubing. It is recommended that a separate surgical field for the abdominal incision is used to reduce the risk of infection (Gregorcyk 2005). The balloon is then filled with an appropriate amount of radiopaque fluid (Parker et al 2003).

After 6 weeks, or when the surgical wounds are healed, the device is activated during an outpatient visit (Parker et al 2003). The cuff is filled with fluid to occlude the anal canal, resulting in continence. Cuff pressure is maintained by the pressure-regulating balloon (Wong et al 1996). When the patient wishes to defecate, the control pump is depressed several times to displace the fluid out of the cuff and into the pressure-regulating

balloon. As a result, anal pressure is decreased and defecation can proceed. The cuff is slowly filled with fluid over 7–10 minutes, which, once again, occludes the anal canal and achieves continence (Wong et al 1996).

Appropriate bowel preparation is essential to reduce the risk of infection. A pre- and post-operative antibiotic regimen is recommended, and a rigid sigmoidoscopy is performed to remove any residual effluent from the rectum prior to skin preparation. Frequent irrigation with antibiotic solution is also recommended throughout the procedure. Implantation should not continue if poor bowel preparation is apparent (Gregorcyk 2005).

Figure 1 Placement of the artificial bowel sphincter



Source: Kamm 1998

Intended purpose

Acticon artificial bowel sphincters are indicated for post-pubescent patients with clinically determined severe faecal incontinence, for whom conservative and other less invasive forms of treatment are contraindicated or have failed.

Indications for implantation of the device are severe faecal incontinence resulting from:

- hereditary malformations such as spina bifida or anal atresia;
- neurological damage as a result of diseases such as diabetic neuropathy, multiple sclerosis, myasthenia gravis and cauda equina neurinoma;
- destruction of the external anal sphincter due to obstetric or iatrogenic trauma; or
- absence of sphincter or neuropathy in the absence of a sphincter defect.

The device is contraindicated in patients:

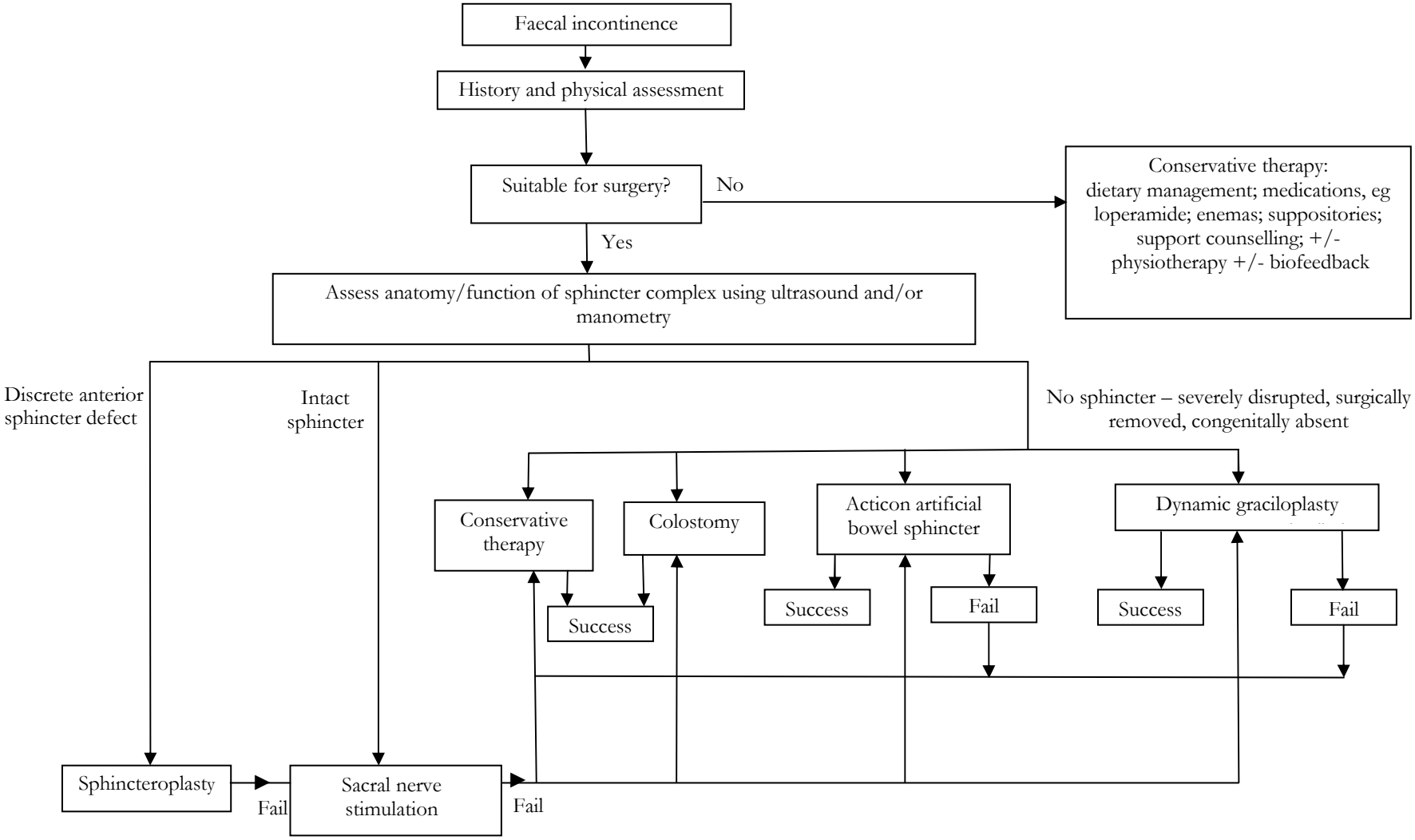
- with inflammatory bowel disease;
- with pelvic sepsis;
- with pregnancy;
- who have an adverse reaction to radiopaque solution (the filling medium for the prosthesis);
- with progressive degenerative diseases;
- with a scarred or fragile perineum; or
- who engage in receptive anal intercourse.

The prosthesis is controlled by manual operation of the pump and therefore requires some dexterity and strength on behalf of patients. This may be a consideration for patient selection (Rotholtz & Wexner 2001).

Existing procedures

The clinical decision-making process concerned with the treatment and diagnosis of patients with faecal incontinence is presented in Figure 2.

Figure 2 Clinical decision tree for faecal incontinence



Note: 'Fail' indicates that satisfactory improvement in continence has not been achieved for the patient.

A number of therapeutic options are available for the treatment of faecal incontinence ranging from conservative medical therapies to surgery. It is recommended that all patients should be offered conservative treatment initially, as there is a degree of uncertainty regarding the long-term success of the more invasive treatment options (Maslekar et al 2006; Rogers et al 2006).

Conservative therapy attempts to treat faecal incontinence that is caused primarily by either constipation or diarrhoea, and can initially involve the use of incontinence pads and dietary management. For patients who suffer from rectal hyposensitivity, increasing stool bulk through the use of bulking agents or fibre supplements (eg psyllium) may be of benefit. However, for some patients, this may exacerbate the problem, in which case anti-diarrhoeal agents such as loperamide can be used. Faecal incontinence caused by impaction often responds to digital evacuation followed by treatment for constipation including increased fibre and fluid intake (Scarlett 2004).

Biofeedback is another form of conservative therapy. The aim of biofeedback is to improve sphincter function using physiological feedback devices to provide the patient with information regarding the efficacy of external sphincter contraction (Kamm 2002; Rogers et al 2006). It has been reported that symptoms of faecal incontinence are reduced in up to two-thirds of patients after biofeedback. It should be the first treatment option for symptoms of mild to moderate incontinence after failure of conservative therapy (Norton & Kamm 2001).

When conservative, less invasive methods of treatment fail, surgical options for severe faecal incontinence can be considered. Sphincteroplasty repairs damage or defects in the external sphincter muscle, achieving continence in 60–80 per cent of patients. However, the long-term success of the procedure is disappointing, with only 50 per cent of patients with an initial successful outcome maintaining improved continence after 5 years, and only 6 per cent after 10 years (Maslekar et al 2006; Muller et al 2005).

Sacral nerve stimulation was first reported in 1995 by Matzel and colleagues. The aim of this procedure is to provide continuous low level stimulation of the sacral nerve through the implantation of electrodes (Kamm 2002). The goal is to improve contraction of the pelvic floor muscles and, hence, continence. The procedure is performed in a number of stages, firstly to determine the optimum site for stimulation and then to connect to an external pulse generator for test stimulation. If adequate improvement is seen, a permanent pulse generator is implanted (Madoff et al 2004; Tjandra et al 2004).

Comparator

Three comparators were identified as possibly being replaced by an Acticon ABS implantation procedure – conservative therapy, surgery (dynamic graciloplasty) and colostomy.

Conservative therapy for severe faecal incontinence requires a combination of a number of methods to help maintain a degree of continence and to improve quality of life. Dietary advice is given in order to maintain a firm consistency of stools, and obtain regular defecatory patterns. Biofeedback or physiotherapy is provided to assist the retraining of pelvic floor or sphincter muscles. Advice on incontinence aids, odour management and skin hygiene is also provided to the patient (O'Brien et al 2004).

Graciloplasty is the transposition of the gracilis muscle from the leg to act as a neosphincter, and was first described in the 1950s. Problems with long-term

effectiveness led to implantation of an electrical device to stimulate the muscle, which was first reported in the 1980s (Maslekar et al 2006). Electrical stimulation of the neosphincter allows tonic contraction to be maintained over prolonged periods without conscious effort by the patient (Madoff et al 1992).

Colostomy is a faecal diverting procedure which connects part of the colon to the anterior abdominal wall via a stoma (Borwell 1996). Faecal matter exits the body via the stoma, and collects in a pouch which is routinely changed by the patient. Because colostomy does not aim to restore faecal continence, it is an option that is considered when all other treatments have failed.

Marketing status of the device/technology

The Acticon ABS prosthesis is registered on the Australian Register of Therapeutic Goods (ARTG Number 12950).

Current reimbursement arrangement

Currently, there is no listing on the Medicare Benefits Schedule (MBS) for the Acticon ABS or other artificial bowel sphincters. In addition, there is no listing for conservative therapy for the treatment of severe faecal incontinence, although this would be covered under items regarding consultation with specialist physicians. The following are the MBS item numbers which are relevant for the reimbursement of dynamic graciloplasty, colostomy and conservative therapy. Costing of the actual procedures and therapy is performed in the 'economic considerations' section of this report.

Dynamic graciloplasty

Item 32203	Anal or perineal graciloplasty (Anaes.) (Assist.) Fee: $549.
Item 32206	Stimulator and electrodes, insertion of, following previous graciloplasty (Anaes.) (Assist.) Fee: $496.50
Item 32209	Anal or perineal graciloplasty with insertion of stimulator and electrodes (Anaes.) (Assist.) Fee: $797.90
Item 32210	Gracilis neosphincter pacemaker, replacement of (Anaes.) Fee: $221.10

Source: Medicare Australia 2006

Colostomy

Item 32000	Large intestine, resection of, without anastomosis, including right hemicolectomy (including formation of stoma) (Anaes.) (Assist.) Fee: $911.35
Item 32030	Rectosigmoidectomy (Hartmann's operation) (Anaes.) (Assist.) Fee: $911.35
Item 30375	Caecostomy, Enterostomy, Colostomy, Enterotomy, Colotomy, Cholecystostomy, Gastrostomy, Gastrotomy, Reduction of intussusception, Removal of Meckel's diverticulum, Suture of perforated peptic ulcer, Simple repair of ruptured viscus, Reduction of volvulus, Pyloroplasty (adult) or Drainage of pancreas (Anaes.) (Assist.) Fee: $460.55

Source: Medicare Australia 2006

Conservative treatment

Item 110	Consultant physician (other than in psychiatry), referred consultation - surgery or Hospital (Professional attendance at consulting rooms or hospital by a consultant physician in the practice of his or her specialty (other than in psychiatry) where the patient is referred to him or her by a medical practitioner) - INITIAL attendance in a single course of treatment Fee: $133.35
Item 116	Each attendance (other than a service to which item 119 applies) SUBSEQUENT to the first in a single course of treatment Fee: $66.75

Source: Medicare Australia 2006

Approach to assessment

Objective

To determine whether there is sufficient evidence, in relation to clinical need, safety, effectiveness and economic considerations, to have implantation of the Acticon ABS for the treatment of severe faecal incontinence listed on the MBS.

Research questions

1. What is the clinical need / burden of disease for implantation of the Acticon ABS for the treatment of severe faecal incontinence?

2. Is implantation of the Acticon ABS for the treatment of severe faecal incontinence as safe as, or safer than, dynamic graciloplasty, colostomy or conservative therapy?

3. Is implantation of the Acticon ABS as efffective as, or more effective than, dynamic graciloplasty, colostomy or conservative therapy for the treatment of severe faecal incontinence?

4. Is implantation of the Acticon ABS as cost-effective as, or more cost-effective than, dynamic graciloplasty, colostomy or conservative therapy for the treatment of severe faecal incontinence?

Expert advice

An advisory panel with expertise in general practice, geriatrics, consumer issues, health administration and colorectal surgery was established to evaluate the evidence and provide advice to the MSAC from a clinical perspective. In selecting members for advisory panels, the MSAC's practice is to approach the appropriate medical colleges, specialist societies and associations and consumer bodies for nominees. Membership of the advisory panel is provided at Appendix B.

Review of literature

Literature sources and search strategies

Implantation of an artificial sphincter for the management of faecal incontinence was first mentioned in the literature in 1996. Thus, the medical literature was searched to identify relevant studies and reviews for the period between 1996 and April 2007. Appendix C describes the electronic databases that were used for this search and the other sources of evidence that were investigated.

The search terms used to identify literature in electronic databases on the safety and effectiveness of the Acticon ABS are also presented in Appendix C.

Inclusion/exclusion criteria

The criteria for including articles in this report varied depending on the type of research question being addressed. Often a study was assessed more than once because it addressed more than one research question. One researcher applied the inclusion

criteria to the collated literature. If there was any doubt concerning inclusion of papers, this was resolved by group consensus to ensure that all potentially relevant studies were captured. In general, studies were excluded if they:

- did not address the research question;
- did not provide information on the pre-specified target population;
- did not include the pre-specified intervention, ie the Acticon ABS as opposed to the modified urinary sphincter or other artificial anal sphincter. Some studies included patients who received either the Acticon ABS or the modified urinary sphincter; such studies were included as they had included the intervention of interest;
- did not compare results to the pre-specified comparators;
- did not address one of the pre-specified outcomes and/or provided inadequate data on these outcomes (in some instances, a study was included to assess one or more outcomes but had to be excluded for other outcomes due to data inadequacies); or
- did not have the study design specified in the inclusion criteria in the protocol.

The inclusion criteria relevant to each of the research questions posed in this assessment are provided in Box 1 to Box 3 in the Results section of this report.

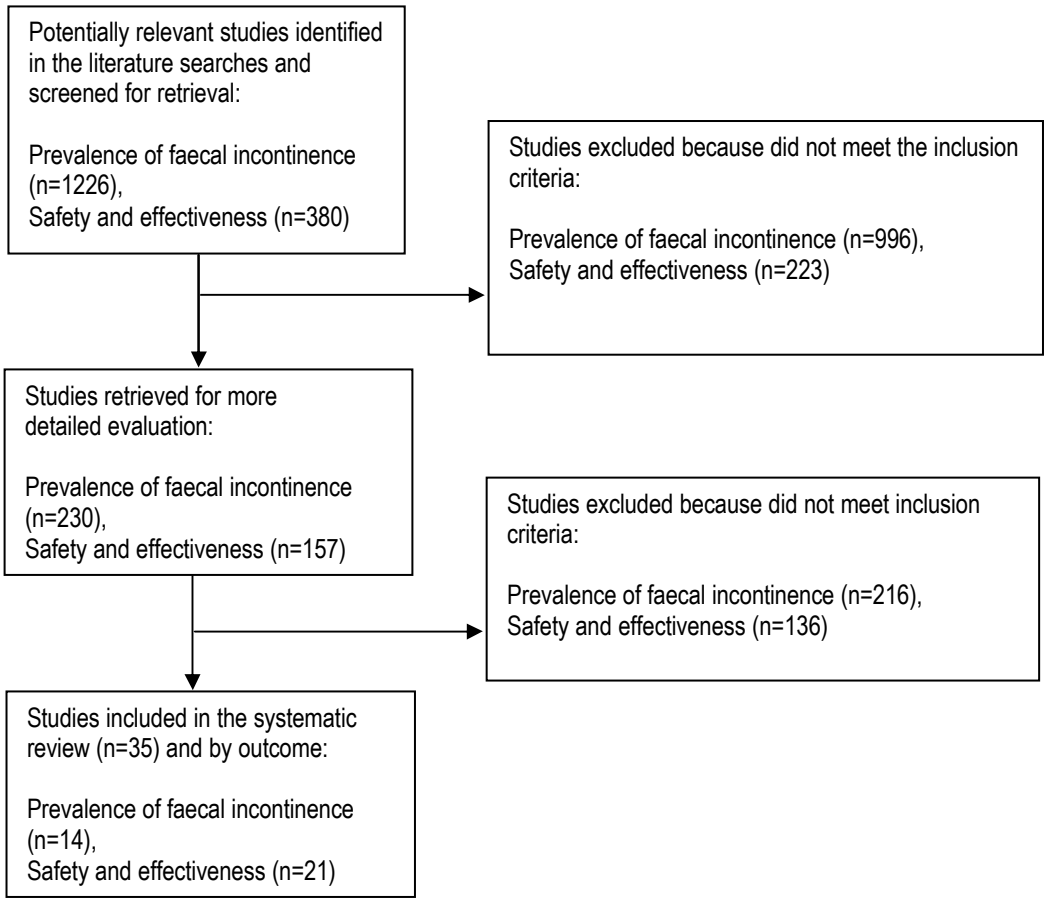
Search results

The process of study selection for this report went through six phases:

1. All reference citations from all literature sources were collated into an Endnote 8.0 database.
2. Duplicate references were removed.
3. Studies were excluded, on the basis of the citation information, if it was obvious that they did not meet the pre-specified inclusion criteria. Citations were assessed independently by two reviewers. Studies marked as requiring further evaluation by either reviewer (after discussion) were retrieved for full-text assessment.
4. Studies were included to address the research questions if they met the pre-specified criteria again independently applied by two reviewers to the full-text articles. Those articles meeting the criteria formed part of the evidence-base. The remainder provided background information.
5. The reference lists of the included articles were pearled for additional relevant studies. These were retrieved and assessed according to phase 4.
6. The evidence-base consisted of articles from phases 4 and 5 that met the inclusion criteria.

Any doubt concerning inclusions at phase 4 was resolved by consensus between the two reviewers. A third reviewer was included to arbitrate where necessary. The results of the process of study selection are provided in Figure 3.

Figure 3 Study selection process



Data extraction and analysis

A profile of key characteristics was developed for each included study (Appendix D).

Burden of disease has been reported as the prevalence of faecal incontinence within Australia (and New Zealand).

Descriptive statistics were extracted or calculated for all safety and effectiveness outcomes (defined in the assessment protocol) in the individual studies, including numerator and denominator information, means and standard deviations. Medians and interquartile ranges were reported for data that were not normally distributed. A statistically significant difference was assumed at $p<0.05$.

Assessment of effectiveness was largely concerned with determining whether there were improvements in faecal incontinence from baseline. Differences between the intervention group and comparator at baseline have been considered to ensure that results reflect a real change due to the intervention rather than the result being affected by baseline differences between treatment groups. In instances where both baseline and follow-up data were provided for an outcome in intervention and comparator groups, the absolute difference between the pre- and post-intervention scores has been calculated.

The majority of studies in this report were uncontrolled pre-test/post-test case series. Effectiveness data from both pre- and post-intervention have been presented, as well as the absolute difference and the results of any statistical testing conducted by the authors.

Validity assessment of individual studies

The evidence presented in the selected studies was assessed and classified using the dimensions of evidence defined by the National Health and Medical Research Council (NHMRC 2000a).

These dimensions (Table 3) consider important aspects of the evidence supporting a particular intervention and include three main domains: strength of the evidence, size of the effect and relevance of the evidence. The first domain is derived directly from the literature identified as informing a particular intervention. Each of the last two requires expert clinical input as part of its determination.

Table 3 Evidence dimensions

Type of evidence	Definition
Strength of the evidence	
Level	The study design used, as an indicator of the degree to which bias has been eliminated by design.[a]
Quality	The methods used by investigators to minimise bias within a study design.
Statistical precision	The *p*-value or, alternatively, the precision of the estimate of the effect. It reflects the degree of certainty about the existence of a true effect.
Size of effect	The distance of the study estimate from the 'null' value and the inclusion of only clinically important effects in the confidence interval.
Relevance of evidence	The usefulness of the evidence in clinical practice, particularly the appropriateness of the outcome measures used.

[a] See Table 4

Strength of the evidence

The three subdomains (level, quality and statistical precision) are collectively a measure of the strength of the evidence.

Level

The 'level of evidence' reflects the effectiveness of a study design to answer a particular research question. Effectiveness is based on the probability that the design of the study has reduced or eliminated the impact of bias on the results.

The NHMRC evidence hierarchy provides a ranking of various study designs ('levels of evidence') by the type of research question being addressed (NHMRC 2005). Table 4 is an abbreviated version of this evidence hierarchy and includes the research question relevant to an assessment of an intervention.

Table 4 Designations of intervention levels of evidence adapted from NHMRC (2005)

Level	Intervention [a]
I [b]	A systematic review of level II studies
II	A randomised controlled trial
III-1	A pseudorandomised controlled trial (ie alternate allocation or some other method)
III-2	A comparative study with concurrent controls: non-randomised, experimental trial [c] cohort study case-control study interrupted time series with a control group
III-3	A comparative study without concurrent controls: historical control study two or more single-arm studies [d] interrupted time series without a parallel control group
IV	Case series with either post-test or pre-test/post-test outcomes

Explanatory notes

[a] Definitions of these study designs are provided in NHMRC (2000a; pp. 7–8).

[b] 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.

[c] This also includes controlled before-and-after (pre-test/post-test) studies, as well as adjusted indirect comparisons (ie using A vs B and B vs C to determine A vs C).

[d] Comparing single-arm studies, ie case series from two studies.

Note 1: Assessment of comparative harms/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 randomised 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 2: When a level of evidence is attributed in the text of a document, it should also be framed according to its corresponding research question, eg level II intervention evidence; level IV diagnostic evidence.

Quality

The appraisal of intervention studies pertaining to treatment safety and effectiveness was undertaken using a checklist developed by the NHMRC (2000b). This checklist was used for trials and cohort studies. Uncontrolled before-and-after case series are a poorer level of evidence for the assessment of effectiveness. The quality of this type of study design was assessed according to a checklist developed by the UK National Health Service (NHS) Centre for Reviews and Dissemination (Khan et al 2001).

Statistical precision

Statistical precision was determined using statistical principles. Small confidence intervals and p-values give an indication as to the probability that the reported effect is real and not attributable to chance (NHMRC 2000a).

Size of effect

For intervention studies on implantation of the Acticon ABS, it was important to assess whether statistically significant differences are also clinically important. The size of the effect needed to be determined, as well as whether the 95% confidence interval includes only clinically important effects.

Relevance of evidence

Similarly, the outcome being measured should be appropriate and clinically relevant. Inadequately validated (predictive) surrogate measures of a clinically relevant outcome should be avoided (NHMRC 2000a).

Assessment of the body of evidence

Appraisal of the body of evidence was conducted along the lines suggested by the NHMRC in their guidance on clinical practice guideline development (NHMRC 2007). Five components are considered essential by the NHMRC when judging the body of evidence:

- the evidence-base – which includes the number of studies sorted by their methodological quality and relevance to patients;
- the consistency of the study results – whether the better quality studies had results of a similar magnitude and in the same direction, ie homogenous or heterogenous findings;
- the potential clinical impact – appraisal of the precision, size and clinical importance or relevance of the primary outcomes used to determine the safety and effectiveness of the test;
- the generalisability of the evidence to the target population; and
- the applicability of the evidence – integration of this evidence for conclusions about the net clinical benefit of the intervention in the context of Australian clinical practice.

A matrix for assessing the body of evidence for each research question, according to the components above, was used for this assessment (Table 5) (NHMRC 2007).

Table 5 Body of evidence assessment matrix

Body of evidence / Component	A Excellent	B Good	C Satisfactory	D Poor
Evidence-base	Several level I or II studies with low risk of bias	One or two level II studies with low risk of bias, or a SR/multiple level III studies with low risk of bias	Level III studies with low risk of bias, or level I or II studies with moderate risk of bias	Level IV studies, or level I to III studies with high risk of bias
Consistency	All studies consistent	Most studies consistent and inconsistency may be explained	Some inconsistency reflecting genuine uncertainty around clinical question	Evidence is inconsistent
Clinical impact	Very large	Substantial	Moderate	Slight or restricted
Generalisability	Population(s) studied in body of evidence is/are the same as the target population	Population(s) studied in the body of evidence is/are similar to the target population	Population(s) studied in body of evidence is/are different to target population for guideline, but it is clinically sensible to apply this evidence to target population	Population(s) studied in body of evidence is/are different to target population, and it is hard to judge whether it is sensible to generalise to target population
Applicability	Directly applicable to Australian healthcare context	Applicable to Australian healthcare context with few caveats	Probably applicable to Australian healthcare context with some caveats	Not applicable to Australian healthcare context

Results of assessment

What is the clinical need / burden of disease?

It was realised when developing the protocol for this assessment that studies reporting the prevalence of *severe* faecal incontinence were unlikely to be identified. Therefore, a review of the prevalence of faecal incontinence more generally was conducted. Sufficient evidence was available to limit this assessment to studies reporting on prevalence within the Australian population. Studies were included in this assessment according to the criteria outlined in Box 1.

Box 1 Study selection criteria to determine the prevalence of faecal incontinence within Australia

Research question	
What is the prevalence of faecal incontinence among adults within Australia?	
Selection criteria	**Inclusion criteria**
Population	Post-pubescent population in (1) Australia or, if this information is unavailable, (2) Western countries of similar demographic composition
Intervention	N/A
Comparator	N/A
Outcome	Prevalence or incidence of faecal incontinence
Language	Studies relevant to Australia's demographic composition are most likely to be published in English. Therefore, studies in languages other than English were not included.
Limits	Human; 1997 – 1/2007

N/A=not applicable

Fourteen studies evaluating the prevalence of faecal incontinence in Australia were found. Of these, seven determined the prevalence in the general population and seven assessed the prevalence in populations considered to have an increased risk of developing faecal incontinence. For the purpose of this review, a study by Lynch et al (2001) on a New Zealand population has been included as it was considered that this population is generalisable to Australia. Much variability in the definition of faecal incontinence has been apparent in studies included in this assessment. As such, the populations of these studies may not necessarily reflect the population that would be suitable for implantation of the Acticon ABS.

The prevalence of faecal incontinence among the general Australian population ranges from 3 per cent to 16 per cent (Table 6). However, comparison between the studies is problematic due to the variability in definitions of faecal incontinence. Interestingly, those studies that incorporated a postal questionnaire into the study design reported a higher prevalence of faecal incontinence than studies which used face-to-face or telephone interviews, suggesting the presence of potential bias in these studies.

A systematic review of studies of prevalence of faecal incontinence included a meta-analysis of community-based studies that had derived age and sex-specific rates of faecal incontinence which were then applied to the Australian population (Chiarelli et al 2005). Pooled estimates, using a random effects model, indicated that the prevalence of faecal incontinence in age-specific strata ranged from 3 per cent to 23 per cent in males, and from 2 per cent to 16 per cent in females. Overall, the prevalence of faecal incontinence in males and females was calculated to be 5.5 per cent and 5.3 per cent respectively.

Unexplained heterogeneity in some age strata suggests that a degree of caution should be used when considering the results of this study.

Of the studies which looked at prevalence in the general population, MacLennan et al (2000) and Avery et al (2004) reported from the same population using data extracted from the 1998 South Australian Health Omnibus survey. These studies reported the lowest prevalence of faecal incontinence within the general Australian population. However, it is possible that the prevalence stated in these two studies has been under-reported, as the sample population did not include hospitals or nursing homes and the data were collected via face-to-face interview. In the study by Avery et al (2004), the age-specific prevalence of faecal incontinence was also reported, clearly showing that the prevalence increases as the population ages.

The study by Lynch et al (2001) reported the greatest prevalence of faecal incontinence (16%) using the Cleveland Clinic incontinence scoring system. This provides a score on a scale of 0 to 20, with 0 indicating perfect continence and a score of 20 indicating complete incontinence. The authors used a score of 3 or more to indicate a significant incontinence problem. The median score in this study was 1, and scores ranged between 0 and 13. Surprisingly, subjects who indicated they suffered daily faecal incontinence (≥1/day) did not report daily lifestyle alteration.

The study by Lam et al (1999) reported a prevalence of faecal incontinence of 15 per cent. In considering this result, it is important to note that the definition of faecal incontinence used was one which included incontinence to flatus as well as stool. Interestingly, this study reported a higher prevalence of faecal incontinence in men (20%) than in women (15%).

Table 6 Prevalence of faecal incontinence in the general Australian population

Study	Location and prevalence tool	Definition of faecal incontinence	Population	Prevalence of faecal incontinence
(Avery et al 2004) Same population as (MacLennan et al 2000)	South Australia, Australia 1998 South Australian Health Omnibus Survey	Loss of control of bowel motions	General adult (n=3,010)	Faecal incontinence=3% Females=4% Males=2% Age-specific prevalence: 15–29 years=1% 30–39 years=2% 40–49 years=4% 50–59 years=3% 60–69 years=6% 70–79 years=4% 80+ years=7%
(Boyce et al 2006)	Penrith, New South Wales, Australia Modified Bowel Disease Questionnaire	Self-reported faecal incontinence that had been present for at least 12 weeks of the previous year (Rome II criteria)	General adult (n=762)	Faecal incontinence=8%
(Chiarelli et al 2005) [a] Systematic review	Australia	Varied according to individual study	General adult (n=4,951)	Faecal incontinence=5% Males=6% <30 years=3% 30–39 years=8% 40–49 years=7% 50–59 years=11% 60–69 years=10% 70–79 years=12% 80+ years=23% Females=5 % <30 years=2% 30–39 years=5% 40–49 years=8% 50–59 years=11% 60–69 years=14% 70–79 years=11% 80+ years=16%
(Kalantar et al 2002)	Western Sydney, Australia Modified Bowel Disease Questionnaire	Involuntary loss of anal sphincteric control that led to unwanted release of liquid or solid faeces (not flatus) at an inappropriate time or in an inappropriate place in the previous 12 months	General adult (n=651)	Faecal incontinence=11% [b] Females=12% Males=11% Liquid faecal incontinence=9% [b] Females=9% Males=9% Solid faecal incontinence=2% [b] Females=1% Males=3%
(Lam et al 1999)	Southern Sydney, Australia Bowel Symptom Questionnaire	Positive answer to at least 2 of 3 questions which incorporated stool leakage, wearing a pad for faecal soiling or >25% incontinence of flatus	General adult (n=618)	Faecal incontinence=15% Female=11% <65 years=10% >65 years=14% Males=20% <65 years=N/A >65 years=N/A
(Lynch et al 2001)	Canterbury, New Zealand Questionnaire which incorporated the Cleveland Clinic continence scale	A score ≥ 3 using the Cleveland Clinic incontinence scoring system	General adult (n=717)	Faecal incontinence=16% Females=16% Males=17%
(MacLennan	South Australia,	Loss of control of motions within the	General adult	Faecal incontinence=3%

Study	Location and prevalence tool	Definition of faecal incontinence	Population	Prevalence of faecal incontinence
et al 2000)	Australia 1998 South Australian Health Omnibus Survey	last year	(n=3,010)	Females=3% Males=2%

N/A = raw data not available

[a] Three of four studies included in this study are also included in this review (Kalantar et al 2002; Lam et al 1999; MacLennan et al 2000);

[b] incomplete data for nine responders

Seven studies reported the prevalence of faecal incontinence in populations considered to be at increased risk (Table 7). These populations were people with diabetes mellitus, cystic fibrosis, spinal cord injury, following radiation therapy for prostate cancer, attending a gynaecological or colorectal clinic as outpatients, and women after high-risk labour. The reported prevalence among these populations ranged between 0 per cent and 41 per cent.

The study by Talley et al (2002) attempted to classify gastrointestinal symptoms, including faecal incontinence, in people with diabetes mellitus (predominately Type 2) according to the Rome I criteria. These criteria provide a standard for the classification and diagnosis of functional gastrointestinal disorders (Drossman & Dumitrascu 2006). The study assessed the prevalence of faecal incontinence at two time points 3 years apart. The prevalence of self-reported faecal incontinence at baseline and 3 years later was 7 per cent. However, it should be noted that prevalence fluctuated throughout the study, and those subjects who reported faecal incontinence at baseline did not necessarily report it at the 3-year follow-up.

In contrast, Bytzer et al (2001) reported a prevalence of faecal incontinence of 3 per cent in a similar population. The disparity between these two studies may be explained by the use of a disease-specific tool to measure gastrointestinal symptoms by Talley et al (2002).

Chiarelli et al (2003) investigated the prevalence of faecal incontinence in post-partum women who experienced a high-risk delivery, considered to be one which required forceps or ventouse assistance, or delivery of a high birthweight infant. Prevalence of faecal incontinence at 12 months post-partum was reported to be 7 per cent, with a higher prevalence seen in multiparous women (8.5%) compared to primiparous women (5.4%).

Table 7 Prevalence of faecal incontinence in higher risk populations in Australia

Study	Location and prevalence tool	Definition of faecal incontinence	Population	Prevalence of faecal incontinence
Chronic disease				
(Bytzer et al 2001)	Sydney, Australia Modified Bowel Disease Questionnaire	Self-reported faecal incontinence that had been troublesome in the preceding 3 months. A positive answer was recorded if the symptom was reported to occur often or very often	Adults with diabetes mellitus (n=423)	Diabetic subjects=3% Non-diabetic subjects=1%
(Talley et al 2002)	Australia Diabetes Bowel Symptom Questionnaire	Rome I criteria [a]	Adults with diabetes mellitus (n=540)	Faecal incontinence=7% At baseline=7% At 3 years=7%
(White et al 2000)	Adelaide, Australia Validated and modified questionnaire which incorporated the Symptom Severity Index & Symptom Impact Index for stress incontinence in women	Having ever leaked faeces	Adults with cystic fibrosis (n=71)	Faecal incontinence=1% Females=0% Males=2%
Post-partum women				
(Chiarelli et al 2003)	New South Wales, Australia Structured interview to measure experiences of faecal incontinence	A response of 'once a month or less'; 'once a week or less'; 'most days'; or 'every day' to either 'Do you ever accidentally pass solid bowel motions into your underwear?' or 'Do you ever accidentally pass liquid bowel motions into your underwear?'	Women at 12 months post-partum (n=568)	Any faecal incontinence=7% Primiparous=5% Multiparous=9% Incontinent to solid stool=3% Primiparous=2% Multiparous=3% Incontinent to liquid stool=5% Primiparous=4% Multiparous=6%
Spinal cord injury				
(Ng et al 2005)	Sydney, Australia Rome II Integrative Questionnaire; and Burwood Bowel Dysfunction	Recurrent uncontrolled passage of faecal material for at least 1 month in an individual with a developmental age of at least 4 years, and	Patients with spinal cord injury (n=110)	Faecal incontinence=41%

Study	Location and prevalence tool	Definition of faecal incontinence	Population	Prevalence of faecal incontinence
	after Spinal Cord Injury	associated with faecal impaction, diarrhoea or non-structural anal sphincter dysfunction		
Post-radiation therapy for prostate cancer				
(Yeoh et al 2004)	Adelaide, Australia Questionnaire developed to assess symptoms	Not stated	Prostate cancer patients post-radiation therapy (n=38)	Faecal incontinence: Pre RT [b]=5% 4–6 weeks post-RT=39% 1 year post-RT=29% 2 years post-RT=26%
Other				
(Ho et al 2005)	Rural North Queensland, Australia Questionnaire specifically designed and pre-tested for this study	Accidental soiling of clothes or underclothes with faeces	Colorectal surgical and gynaecological outpatient clinics (n=435)	Faecal incontinence=21%

[a] Rome criteria are diagnostic criteria for functional gastrointestinal disorders; [b] radiation therapy

Summary – Prevalence of faecal incontinence among adults within Australia

Determining the prevalence of faecal incontinence in Australia proved to be problematic due to variation in the definition of faecal incontinence used within the studies. Some studies incorporated flatus into their definition while others restricted this to varying degrees of liquid or solid faecal incontinence. Fourteen studies reporting on the prevalence of faecal incontinence among adults in Australia were identified in this review. Seven studies reported on the prevalence within the general population and, of these, two (Avery et al 2004; MacLennan et al 2000) reported on the same population sample.

Reported prevalence of faecal incontinence within the general Australian population ranged from 3 per cent to 16 per cent. As indicated previously, the definition of faecal incontinence varied greatly among these studies, making comparison difficult. It is apparent from the age-specific prevalence rates reported that faecal incontinence increases with age (Avery et al 2004; Chiarelli et al 2005).

With the exception of the study by Lam et al (1999), comparison between male and female groups indicates that there is no difference by sex in the prevalence of faecal incontinence. The higher rates reported by Lam et al (1999) may be explained by the use of a definition of faecal incontinence that included a positive answer to at least two of three questions on stool leakage, wearing a pad for faecal soiling or frequent incontinence of flatus.

Several studies reported high prevalence of faecal incontinence among a number of groups of patients. In particular, these included people with spinal cord injury or diabetes, multiparous women, and men who have received radiotherapy for the treatment of prostate cancer.

Expert opinion indicates that the prevalence of solid faecal incontinence (2%) reported in the

study by Kalantar et al (2002) is likely to be representative of the prevalence of severe faecal incontinence within Australia. Of this population, less than half would be expected to be suitable candidates for implantation of the Acticon ABS.

The variation in definitions used for faecal incontinence, and the wide range of prevalence reported, indicate that these estimates of faecal incontinence may not be reliable.

An alternative approach of using the current practice in the operative comparator (dynamic graciloplasty) may provide a more appropriate estimate of the clinical need for implantation of the Acticon ABS. Recent Medicare statistics indicate that an average of four dynamic graciloplasty procedures have been performed annually within Australia (Medicare Australia 2007a).

Expert opinion suggests that the significant discrepancy between clinical need and expected uptake of implantation of the Acticon ABS can be explained by a number of factors including:

- Many patients do not seek treatment for severe faecal incontinence due to the embarrassment and social stigma associated with the condition, and many also accept it as part of the ageing process.
- Many medical practitioners fail to identify or further investigate this condition; subsequently, many patients are not aware of treatment options.

Is it safe?

Implantation of the Acticon ABS was assessed in terms of potential patient harms that may result from the procedure in both the short and long terms. Studies addressing this issue were assessed for inclusion in this report according to the criteria defined a priori in Box 2. For the purposes of this assessment, the outcomes considered have been prioritised into primary and secondary safety outcomes, and the post-operative period has been considered to be the 6 weeks following implantation or the period between implantation and activation.

Box 2 Inclusion criteria for identification of studies relevant to an assessment of the safety of implantation of the Acticon ABS in the treatment of severe faecal incontinence

Research question

Is implantation of the Acticon ABS as safe as, or safer than, dynamic graciloplasty, conservative therapy or colostomy for patients with severe faecal incontinence?

Selection criteria	Inclusion criteria
Population	Post-pubescent patients with clinically determined severe faecal incontinence
Intervention	Implantation of Acticon ABS
Comparator(s)	Dynamic graciloplasty, conservative therapy or colostomy
Outcomes	Primary outcomes: Mortality; infection; explantation; problematic pain; surgical revision; erosion (short- and long-term (> 12 months))
	Secondary outcomes: Adverse events including obstructed defecation; other adverse events (short- and long-term (> 12 months))
Study design	Randomised or non-randomised controlled trials, cohort studies, registers, case series, case reports or systematic reviews of these study designs
Search period	1996 – 4/2007
Language	Studies in languages other than English were only translated and included if they represented a higher level of evidence than that available in the English language evidence-base.

Data from studies have been extracted into Tables 8 to 14 to describe the comparison of relevant outcomes, and ordered in a hierarchical manner according to each study's level of evidence, quality assessment, alphabetical listing and most recent publication date.

A systematic review published by Mundy et al (2004) reported on the safety associated with implantation of the Acticon ABS. At the time, no comparative studies had been published in relation to the Acticon ABS; therefore, the review simply reported on the adverse events relating to this procedure. Unlike this present assessment, the review by Mundy et al (2004) also included studies which implanted the modified urinary sphincter. Due to the increased volume of published literature regarding the Acticon ABS, this assessment does not include such studies (Mundy et al 2004)

In total, 21 studies reported on adverse events relating to implantation of the Acticon ABS. Of these, one was a randomised controlled trial and two were non-randomised comparative studies, one with concurrent controls (Ortiz et al 2003) and the other using historical controls (da Silva et al 2004). Also included in this assessment of safety were 16 uncontrolled case series and two case reports. No studies were identified which compared implantation of the Acticon ABS to colostomy.

Primary safety outcomes

Mortality

No studies were identified which reported death, either post-operatively or during follow-up, as a result of implantation of the Acticon ABS.

Infection

The invasive nature and site of implantation of the Acticon ABS leads to the reasonable assumption that infection would be a significant complication associated with the procedure. Many studies indicate, as well as advocate, the use of a prophylactic antibiotic regimen to prevent infection associated with this procedure.

Not all identified studies reported infection as a result of implantation of the Acticon ABS. Of the 19 studies which reported on complications associated with this procedure, 15 reported infection as a complication (Table 8). In 457 patients who received the Acticon ABS, there were 100 infections (22%). Infection rates in the studies ranged from 0 per cent to 46 per cent (not including case reports). It should be noted that a number of studies had an overlap of patients.

Three comparative studies were identified, two comparing the Acticon ABS with dynamic graciloplasty (da Silva et al 2004; Ortiz et al 2003) and the other with conservative therapy (O'Brien et al 2004).

The study by O'Brien et al (2004) was a good quality randomised controlled trial (level II intervention evidence) comparing implantation of the Acticon ABS with provision of conservative therapy in an Australian setting. Although small numbers were involved in this study, no infections resulting from these invasive procedures were reported. This may be attributed to the author's 'vigorous attention' to infection control including antiseptic washing, exclusion of the anal canal from the operating field and prophylactic antibiotic administration (O'Brien et al 2004). It may also be due to the short-term patient follow-up in the study.

Two studies, both of fair quality, compared implantation of the Acticon ABS to dynamic graciloplasty, firstly in a non-randomised study with a concurrent comparator (level III-2 intervention evidence; Ortiz et al 2003), and secondly in a non-randomised study using historical records for the comparator (level III-3 intervention evidence; da Silva et al 2004).

The fair quality study by Ortiz et al (2003) reported infection only in those patients receiving dynamic graciloplasty. Infection rates for the Acticon ABS and dynamic graciloplasty were 0 per cent (0 of 8) and 38 per cent (3 of 8) respectively. It is notable that there is a marked difference between these two groups despite both receiving antibiotic prophylaxis and both procedures being performed by the same two surgeons.

Da Silva et al (2004) reported, in a fair quality comparative study (level III-3 intervention evidence), infection rates of the Acticon ABS and dynamic graciloplasty to be 9 per cent and 20 per cent respectively. In this study eight patients were followed prospectively and eight were reviewed retrospectively using medical records and postal and/or telephone interviews during follow-up. The eight prospectively recruited subjects all received the Acticon ABS; of the retrospectively recruited subjects, three received the Acticon ABS

and five received dynamic graciloplasty. The use of medical records introduces the potential for error as it is widely acknowledged that such records may not provide all the relevant information required for research purposes (Gordis 2004). In this case, the post-operative reporting of complications may not be as accurate or precise as those of the prospectively followed patients.

The greatest infection rates were seen in good quality studies published by Parker et al (2003) and Wong et al (2002) reporting Acticon ABS implantation infection rates of 46 and 34 per cent respectively. Both studies were case series (level IV intervention evidence) reporting on 26 patients from a single institution. The reported follow-up period for patients was longer in the study by Parker et al (2003) (mean=39 months v 12 months), which may also contribute to the higher infection rate.

Wong et al (2002) reported on 112 patients who received the Acticon ABS at 19 different institutions in USA, Canada and Europe. At the outset, the type of antibiotic regimen used was at the discretion of investigators at the individual sites. However, an initial high infection rate and subsequent review of the prophylactic antibiotic regimen by an infectious disease specialist resulted in the implementation of a standardised prophylactic regimen at all centres. The authors indicated that this markedly reduced the infection-related revision rate in the study, although not to a statistically significant extent.

Another study with a notable infection rate was conducted by Devesa et al (2002). In this case series of 53 patients, an infection rate of 27 per cent was reported during the mean follow-up period of 26 months. The authors noted that all patients who developed infection required removal of all or part of the device despite extensive culture-guided antibiotic therapy.

Table 8 Infection associated with implantation of the Acticon ABS for severe faecal incontinence

Study	Study design and quality appraisal	Population	Post-operative infection	Infection during follow-up	Total number of infections
(O'Brien et al 2004)	Level II randomised controlled trial Quality assessment: Good	14 patients with severe anal incontinence *Comparator* **Conservative therapy** (n=7)	*Acticon ABS* None reported *Conservative therapy* None reported	*Acticon ABS* None reported *Conservative therapy* None reported	*Acticon ABS* 0/7 (0%) *Conservative therapy* 0/7 (0%)
(Ortiz et al 2003) Note: Overlap between patients with (Ortiz et al 2002)	Level III-2 non-randomised experimental trial Quality assessment: Fair	16 patients with severe faecal incontinence *Comparator* **Dynamic graciloplasty** (n=8)	*Acticon ABS* None reported *Dynamic graciloplasty* Perineal infection=1/8 Infection requiring drainage=2/8	*Acticon ABS* None reported *Dynamic graciloplasty* None reported	*Acticon ABS* 0/8 (0%) *Dynamic graciloplasty* 3/8 (38%)
(da Silva et al 2004)	Level III-3 non-randomised experimental trial Quality assessment: Fair	16 patients with imperforate anus *Comparator* **Dynamic graciloplasty** (n=5)	*Acticon ABS* Wound infection=1/11 *Dynamic graciloplasty* Wound infection requiring surgical debridement=1/5 [a]	*Acticon ABS* None reported *Dynamic graciloplasty* None reported	*Acticon ABS* 1/11 (9%) *Dynamic graciloplasty* 1/5 (20%)
(Parker et al 2003) Note: 26 patients in Group II were previously reported in Wong et al (2002)	Level IV pre-test/post-test case series Quality assessment: Good	47 patients with severe faecal incontinence Group I – 10 patients who underwent implantation between 1989 and 1992 [e] Group II – 37 patients who underwent implantation after 1996	*Acticon ABS* Group II: Infection=7/37 [b]	*Acticon ABS* Infection=5/37 [b] Infection requiring reimplantation=2/37 [b] Infection after cuff replacement=3/37 [ab]	*Acticon ABS* Group II: 17/37 (46%)
(Wong et al 2002)	Level IV pre-test/post-test case series Quality assessment: Good	115 patients with severe faecal incontinence Note: 112 patients were implanted with device	*Acticon ABS* None reported	*Acticon ABS* Infection=38/112 [a]	*Acticon ABS* 38/112 (34%)
(Altomare et al 2004) Note: Patients originally reported in Altomare et al (2001)	Level IV pre-test/post-test case series Quality assessment: Fair	21 patients who had an implanted ABS device at a median of 50 months follow-up	*Acticon ABS* N/A	*Acticon ABS* Late infection=1/21	*Acticon ABS* 1/21 (5%)
(Altomare et al 2001)	Level IV pre-test/post-test case series Quality assessment: Fair	28 patients with severe faecal incontinence	*Acticon ABS* Both perineal and abdominal wound=3/28 [b] Perineal wound only=1/28	*Acticon ABS* Late infection=1/28 [b]	*Acticon ABS* 5/28 (18%)

(Casal et al 2004)	Level IV pre-test/post-test case series Quality assessment: Fair	10 patients with severe faecal incontinence	*Acticon ABS* Infection of perianal wound=1/10 [c] Infection and externalisation of tubing=1/10 [a]	*Acticon ABS* Infection of cuff=1/10 [bd]	*Acticon ABS* 3/10 (30%)
(Devesa et al 2002)	Level IV pre-test/post-test case series Quality assessment: Fair	53 consecutive patients with anal incontinence	*Acticon ABS* Infection=7/53 Fever of unknown origin=1/53 [bd]	*Acticon ABS* Perianal infection=3/53 [bd] Infection surrounding pump=2/53 [bad] Infection at balloon site=1/53 [bd]	*Acticon ABS* 14/53 (26%)
(Dodi et al 2000)	Level IV pre-test/post-test case series Quality assessment: Fair	8 women with severe faecal incontinence	*Acticon ABS* Infection at cuff site=2/8 [b]	*Acticon ABS* None reported	*Acticon ABS* 2/8 (25%)
(Lehur et al 2002) Note: Some overlap of patients with Lehur et al (1998) and Lehur et al (2000)	Level IV pre-test/post-test case series Quality assessment: Fair	16 patients with severe anal incontinence	*Acticon ABS* None reported	*Acticon ABS* None reported	*Acticon ABS* 0/16 (0%)
(Lehur et al 2000) Note: Overlap of four patients with Lehur et al (1998)	Level IV pre-test/post-test case series Quality assessment: Fair	24 patients with severe faecal incontinence	*Acticon ABS* None reported	*Acticon ABS* Infection resulting in explantation=1/24 [ab]	*Acticon ABS* 1/24 (4%)
(Lehur et al 1998)	Level IV pre-test/post-test case series Quality assessment: Fair	13 consecutive patients with severe faecal incontinence 4 patients received the Acticon ABS and 9 patients received the AMS 800 urinary sphincter	*Acticon ABS* Abdominal wound infection=1/13	*Acticon ABS* None reported	*Acticon ABS* 1/13 (8%)
(Michot et al 2003)	Level IV pre-test/post-test case series Quality assessment: Fair	37 patients with severe faecal incontinence Two groups of patients: Group I=12 patients implanted before October 1996 Group II=25 patients implanted between October 1996 and April 2001	*Acticon ABS* Group I: Perineal sepsis=2/12 [b] Group II: Inguinal abscess=1/25 Intra-abdominal abscess complication colostomy closure=1/25	*Acticon ABS* Group I: None reported Group II: Sepsis requiring explantation=2/25 [b]	*Acticon ABS* Group I: 2/12 (17%) Group II: 4/25 (16%) Overall: 6/37 (16%)
(Ortiz et al	Level IV pre-	22 patients with	*Acticon ABS*	*Acticon ABS*	*Acticon ABS*

2002)	test/post-test case series Quality assessment: Fair	severe faecal incontinence	Perineal infection=2/22 [b] One patient required explantation and reimplantation	None reported	2/22 (9%)
(Vaizey et al 1998)	Level IV pre-test/post-test case series Quality assessment: Fair	6 females with severe faecal incontinence	*Acticon ABS* Poor wound healing=1/6 [f]	*Acticon ABS* Infection over balloon site=1/6	*Acticon ABS* 2/6 (33%)
(O'Brien & Skinner 2000)	Level IV pre-test/post-test case series Quality assessment: Poor	13 patients with severe faecal incontinence	*Acticon ABS* Infection=1/13 [b]	*Acticon ABS* Infection=1/13b [a] Infection following erosion of pump=1/13 [b]	*Acticon ABS* 3/13 (23%)
(Savoye et al 2000)	Level IV pre-test/post-test case series Quality assessment: Poor	12 consecutive patients with severe faecal incontinence	*Acticon ABS* None reported	*Acticon ABS* None reported	*Acticon ABS* 0/12 (0%)
(La Torre et al 2004)	Level IV pre-test/post-test case series Quality assessment: Poor	8 patients with severe faecal incontinence, 1 patient with APR	*Acticon ABS* Perineal and abdominal wall infection=1/8	*Acticon ABS* None reported	*Acticon ABS* 1/8 (13%)
(Savoye-Collet et al 2006)	Case report Quality assessment: N/A	61 year old woman with Acticon ABS implanted 6 months previously for severe faecal incontinence	*Acticon ABS* N/A	*Acticon ABS* Infection around artificial sphincter and tubing=1/1	*Acticon ABS* 1/1 (100%)
(Benoist et al 2005)	Case report Quality assessment: N/A	25 year old male with high imperforate anus associated with rectourethral fistula	*Acticon ABS* None reported	*Acticon ABS* None reported	*Acticon ABS* 0/1 (0%)

[a] See also Table 11; [b] see also Table 9; [c] see also Table 14; [d] see also Table 12; [e] results of Group I are not reported as they do not meet inclusion criteria for this review; [f] see also Table 10; APR=abdominoperineal resection; N/A=not applicable; AMS=American Medical Systems

Explantation

Explantation can result from a number of complications including infection, pain, erosion and device malfunction. It is important to keep in mind that explantation can occur as much in the long-term follow-up of patients, particularly as a result of device malfunction, as in the immediate post-operative period. Of 457 patients who received the Acticon ABS to treat severe faecal incontinence, 140 (31%) explantations were performed. Rates of explantation ranged from 0 per cent to 51 per cent and were reported in 16 of 19 included studies (Table 9).

The good quality randomised control trial (level II intervention evidence) by O'Brien et al (2004) reported explantation in 14 per cent of patients. However, the short-term follow-up of 6 months in this study would exclude not only subsequent explantations but any further complications which may have led to explantation.

The two studies which compared the Acticon ABS and dynamic graciloplasty reported dissimilar results in terms of explantation. Ortiz et al (2003), in a fair quality study, reported explantation for the Acticon ABS and dynamic graciloplasty to be 50 per cent each. These results were reported after a median follow-up for the Acticon ABS and dynamic graciloplasty of 44 months and 39 months respectively. In contrast, da Silva et al (2004) reported no explantation of either the Acticon ABS or dynamic graciloplasty. However, this was after a mean follow-up of 12 months and 38 months respectively.

Parker et al (2003), in a good quality study (level IV intervention evidence), only reported the long-term follow-up results (mean=39 months) of patients after implantation of the Acticon ABS. The explantation rate in this study was 68 per cent. Seven of 18 explants occurred post-operatively (within 6 weeks) due to infection, and a further six infections which resulted in explantation occurred during the subsequent follow-up period.

Michot et al (2003) reported on a fair quality, uncontrolled case series of 37 patients (level IV intervention evidence). Of the initial 12 patients in the study, nine received a modified urinary sphincter and three received the Acticon ABS. Patients were followed for a mean of 5 years. The second group of patients all received the Acticon ABS and were followed for a mean of 2.8 years. Although the majority of the first group received devices for which this review is not reporting, the explantation of these patients was 50 per cent. Of the second group, 20 per cent were explanted. Interestingly, the first group was explanted in the post-operative period, while the second group was explanted during the 34 month follow-up period.

Table 9 Adverse events requiring explantation of the Acticon ABS

Study	Study design and quality appraisal	Population	Post-operative explantation	Explantation during follow-up	Total number of explants
(O'Brien et al 2004)	Level II randomised controlled trial Quality assessment: Good	14 patients with severe anal incontinence *Comparator* **Conservative therapy** (n=7)	*Acticon ABS* Failure to heal of perineal wound=1/7 [a] *Conservative therapy* N/A	*Acticon ABS* None reported *Conservative therapy* N/A	*Acticon ABS* 1/7 (14%) *Conservative therapy* N/A
(Ortiz et al 2003) Note: Overlap between patients with (Ortiz et al 2002)	Level III-2 non-randomised experimental trial Quality assessment: Fair	16 patients with severe faecal incontinence *Comparator* **Dynamic graciloplasty** (n=8)	*Acticon ABS* None reported *Dynamic graciloplasty* None reported	*Acticon ABS* Erosion followed by implantation of new device=1/8 [b] Erosion=2/8 Perineal pain=1/8 *Dynamic graciloplasty* Stimulator removed=4/8 Rectal section by tendon=1/4 Perineal pain=1/4 Battery malfunction=1/4 Failure to achieve continence=1/4	*Acticon ABS* 4/8 (50%) *Dynamic graciloplasty* 4/8 (50%)
(da Silva et al 2004)	Level III-3 non-randomised experimental trial Quality assessment: Fair	16 patients with imperforate anus *Comparator* **Dynamic graciloplasty** (n=5)	*Acticon ABS* None reported *Dynamic graciloplasty* None reported	*Acticon ABS* None reported *Dynamic graciloplasty* None reported	*Acticon ABS* 0/11 (0%) *Dynamic graciloplasty* 0/5 (0%)
(Parker et al 2003) Note: 26 patients in Group II were previously reported in Wong et al (2002)	Level IV uncontrolled pre-test/post-test case series Quality assessment: Good	47 patients with severe faecal incontinence Group I – 6/10 patients who underwent implantation between 1989 and 1992 [g] Group II – 37 patients who underwent implantation after 1996	*Acticon ABS* Group II: Infection=7/37 [c]	*Acticon ABS* Group II: Infection=6/35 [c] Pain=2/35 [d] Fluid leak followed by reimplantation=2/37 Cuff leak followed by reimplantation=2/37 Cuff open followed by reimplantation=1/37 Infection followed by reimplantation=2/37 [cd] Infection after cuff replacement=3/37 [ce]	*Acticon ABS* Group II: 25/37 (68%)
(Wong et al 2002)	Level IV uncontrolled pre-test/post-test case series Quality assessment: Good	115 patients with severe faecal incontinence Note: 112 patients were implanted with device	*Acticon ABS* None reported	*Acticon ABS* 41/112 explants Note: Seven patients were reimplanted and retained functioning device at end of follow-up	*Acticon ABS* 41/112 (37%)

(Altomare et al 2004)	Level IV uncontrolled pre-test/post-test case series Quality assessment: Fair	21 patients who had an implanted ABS device at a median of 50 months follow-up Patients originally reported in Altomare et al (2001)	*Acticon ABS* N/A	*Acticon ABS* Definitive explants=4/21 Mechanical failure=2/4 Late infection=1/4 [c] Obstructed defecation=1/4 [f]	*Acticon ABS* 4/21 (19%)
(Altomare et al 2001)	Level IV uncontrolled pre-test/post-test case series Quality assessment: Fair	28 patients with severe faecal incontinence	*Acticon ABS* Both perineal and abdominal wound=3/28 [c] Erosion=1/28 [b]	*Acticon ABS* Erosion=2/28 [b] (cuff replaced in one patient) Late infection=1/28 [cd] Pain=1/28 [d]	*Acticon ABS* 8/28 (29%)
(Casal et al 2004)	Level IV uncontrolled pre-test/post-test case series Quality assessment: Fair	10 patients with severe faecal incontinence	*Acticon ABS* None reported	*Acticon ABS* Infection and erosion of cuff=1/10 [bc] Cuff had lost water tightness=2/10 [a] Note: devices were reimplanted	*Acticon ABS* 3/10 (30%)
(Devesa et al 2002)	Level IV uncontrolled pre-test/post-test case series Quality assessment: Fair	53 consecutive patients with anal incontinence	*Acticon ABS* Urethral fistula followed by skin decubitus=1/53 [ab]	*Acticon ABS* Pain and neurosis=1/53 [d] Perianal infection=3/53 [bc] Pump erosion and infection=2/53 [bc] Balloon erosion and infection=1/53 [bc] Cuff erosion and infection=1/53 [bc] Fever of unknown origin=1/53 Device explanted then reimplanted=3/53 Traumatic rupture of device=1/3 Replaced cuff due to defecating difficulties=1/3 Replaced cuff due to continuing incontinence=1/3	*Acticon ABS* 13/53 (25%)
(Dodi et al 2000)	Level IV uncontrolled pre-test/post-test case series Quality assessment: Fair	8 women with severe faecal incontinence	*Acticon ABS* Infection=2/8 [c]	*Acticon ABS* None reported	*Acticon ABS* 2/8 (25%)
(Lehur et al 2002) Note: Some overlap of patients with Lehur et al	Level IV uncontrolled pre-test/post-test case series Quality assessment:	16 patients with severe anal incontinence	*Acticon ABS* None reported	*Acticon ABS* Definitive explants=4/16 Uncontrolled diarrhoea=1/4 Faecal	*Acticon ABS* 5/16 (31%)

(1998) and Lehur et al (2000)	Fair			leakage=1/4 Unbuttoning of cuff and pain=1/4 [d] Loss of radiopaque fluid=1/4 Erosion of labia=1/16 [b]	
(Lehur et al 2000) Note: Overlap of four patients with Lehur et al (1998)	Level IV uncontrolled pre-test/post-test case series Quality assessment: Fair	24 patients with severe faecal incontinence	*Acticon ABS* Definitive explants=1/24 Erosion of connecting tubes=1/1 [b]	*Acticon ABS* Definitive explants=3/24 Cuff unbuttoning=1/3 [ce] Cuff rupture=1/3 [d] Perineal erosion=1/3 [b] Faecal impaction requiring explant followed by reimplantation with appropriate cuff size=1/24 [f] Ulceration of labia followed by reimplantation 6 months later=1/24 [b] Pump malfunction followed by reimplantation=1/24 Repeated cuff unbuttoning=1/24	*Acticon ABS* 8/24 (33%)
(Lehur et al 1998)	Level IV uncontrolled pre-test/post-test case series Quality assessment: Fair	13 consecutive patients with severe faecal incontinence 4 patients received the Acticon ABS and 9 patients received the AMS 800 urinary sphincter	*Acticon ABS* None reported	*Acticon ABS* Development of ulcerative colitis 5 years after implantation=1/13 Dissatisfaction with device despite good functional results=1/13 [e] Rupture of cuff followed by reimplantation=1/13 [e] Narrow cuff leading to faecal impaction and ulcerated labia=1/13 [f]	*Acticon ABS* 4/13 (31%)
(Michot et al 2003)	Level IV uncontrolled pre-test/post-test case series Quality assessment: Fair	37 patients with severe faecal incontinence Two groups of patients: Group I=12 patients implanted before October 1996 Group II=25 patients implanted between October	*Acticon ABS* Group I: Perineal sepsis=2/12 [c] Pain=1/12 [d] Perineal erosion=3/12 [b] Group II: None reported	*Acticon ABS* Group I: None reported Group II: Sepsis=2/25 [c] Perineal erosion=3/25 [b]	*Acticon ABS* Group I: 6/12 (50%) Group II: 5/25 (20%) Overall: 11/37 (30%)

		1996 and April 2001			
(Ortiz et al 2002)	Level IV uncontrolled pre-test/post-test case series Quality assessment: Fair	22 patients with severe faecal incontinence	*Acticon ABS* Perineal infection=1/22 [c]	*Acticon ABS* Perineal pain=2/22 [d] Exteriorisation=4/22 [b] Repeated unbuttoning of cuff required explantation followed by reimplantation and subsequent explantation=2/22 [be]	*Acticon ABS* 9 explants in 8/22 (36%)
(Vaizey et al 1998)	Level IV uncontrolled pre-test/post-test case series Quality assessment: Fair	6 females with severe faecal incontinence	*Acticon ABS* Ulceration through perianal skin=1/6 [b]	*Acticon ABS* None reported	*Acticon ABS* 1/6 (17%)
(O'Brien & Skinner 2000)	Level IV uncontrolled pre-test/post-test case series Quality assessment: Poor	13 patients with severe faecal incontinence	*Acticon ABS* Infection=1/13 [c]	*Acticon ABS* Infection=2/13 [c]	*Acticon ABS* 3/13 (23%)
(Savoye et al 2000)	Level IV uncontrolled pre-test/post-test case series Quality assessment: Poor	12 consecutive patients with severe faecal incontinence	*Acticon ABS* None reported	*Acticon ABS* None reported	*Acticon ABS* 0/12 (0%)
(La Torre et al 2004)	Level IV uncontrolled pre-test/post-test case series Quality assessment: Poor	8 patients with severe faecal incontinence, 1 patient with APR	*Acticon ABS* None reported	*Acticon ABS* None reported	*Acticon ABS* 0/8 (0%)
(Savoye-Collet et al 2006)	Case report Quality assessment: N/A	61 year old woman with Acticon ABS implanted 6 months previously for severe faecal incontinence	*Acticon ABS* None reported	*Acticon ABS* None reported	*Acticon ABS* 0/1 (0%)
(Benoist et al 2005)	Case report Quality assessment: N/A	25 year old male with high imperforate anus associated with rectourethral fistula	*Acticon ABS* None reported	*Acticon ABS* None reported	*Acticon ABS* 0/1 (0%)

[a] See also Table 14; [b] see also Table 12; [c] see also Table 8; [d] see also Table 10; [e] see also Table 11; [f] see also Table 13; [g] results of Group I are not reported as they do not meet inclusion criteria for this review; APR=abdominoperineal resection; AMS=American Medical Systems; N/A=not applicable

Problematic pain

Problematic pain is considered to be that which is beyond what would be expected and associated with a surgical procedure. In this assessment, problematic pain resulting from implantation of the Acticon ABS was reported in 13 of 19 included studies and occurred

in 59 of 457 (13%) patients who received the device. Reports of problematic pain in the studies ranged from no reports of pain to 33 per cent of patients (Table 10).

Pain associated with this procedure can be caused by a poorly positioned device, and infection or erosion, among other causes. Management can range from analgesia or antibiotics to surgical revision or explantation.

The randomised controlled trial reported by O'Brien et al (2004), comparing the Acticon ABS with conservative therapy, did not report pain as an outcome for either treatment.

Ortiz et al (2003) reported perineal pain in one patient as a late complication which subsequently resulted in explantation. Pain was not reported by any patients in the study conducted by da Silva et al (2004).

The case series (level IV intervention evidence) by Wong et al (2002) reported the highest rate of pain associated with the Acticon ABS device. In this good quality study, 37 of 112 (33%) patients reported 44 pain events in the 12 month follow-up. Of the 37 patients reporting pain as a complication, two required explantation of the device as a direct consequence.

Altomare et al (2004) also reported a high rate of pain associated with implantation of the Acticon ABS. This case series (level IV intervention evidence) was of fair quality and followed up 21 patients, at a median of 50 months, who had been previously studied in 2001. Four of 21 patients reported anal pain (19%) and one patient indicated that they no longer activated the pump as a result. In the original cohort of 28 patients, two reported anal pain, of whom one had the cuff removed (Altomare et al 2001).

Table 10 Problematic pain associated with implantation of the Acticon ABS for severe faecal incontinence

Study	Study design and quality appraisal	Population	Post-operative problematic pain (number of patients)	Problematic pain during follow-up	Total number of problematic pain events
(O'Brien et al 2004)	Level II randomised controlled trial Quality assessment: Good	14 patients with severe anal incontinence *Comparator* **Conservative therapy** (n=7)	*Acticon ABS* Not reported *Conservative therapy* Not reported	*Acticon ABS* Not reported *Conservative therapy* Not reported	*Acticon ABS* Not reported *Conservative therapy* Not reported
(Ortiz et al 2003) Note: Overlap between patients with (Ortiz et al 2002)	Level III-2 non-randomised experimental trial Quality assessment: Fair	16 patients with severe faecal incontinence *Comparator* **Dynamic graciloplasty** (n=8)	*Acticon ABS* Pain=0/8 *Dynamic graciloplasty* Pain=0/8	*Acticon ABS* Pain=1/8 *Dynamic graciloplasty* Pain=0/8	*Acticon ABS* 1/8 (13%) *Dynamic graciloplasty* 0/8 (0%)
(da Silva et al 2004)	Level III-3 non-randomised experimental trial Quality assessment: Fair	16 patients with imperforate anus *Comparator* **Dynamic graciloplasty** (n=5)	*Acticon ABS* Not reported *Dynamic graciloplasty* Not reported	*Acticon ABS* Not reported *Dynamic graciloplasty* Not reported	*Acticon ABS* Not reported *Dynamic graciloplasty* Not reported
(Parker et al 2003) Note: 26 patients in Group II were previously reported in Wong et al (2002)	Level IV, pre-test/post-test case series Quality assessment: Good	47 patients with severe faecal incontinence Group I – 6/10 patients who underwent implantation between 1989 and 1992 [a] Group II – 37 patients who underwent implantation after 1996	*Acticon ABS* Group II: None reported	*Acticon ABS* Group II: Pain=2/37 [b]	*Acticon ABS* Group II: 2/37 (5%)
(Wong et al 2002)	Level IV pre-test/post-test case series Quality assessment: Good	115 patients with severe faecal incontinence Note: 112 patients were implanted with device	*Acticon ABS* 0/112	*Acticon ABS* Pain=44 events in 37/112 [b]	*Acticon ABS* 44 events in 37/112 (33%)
(Altomare et al 2004)	Level IV pre-test/post-test case series Quality assessment: Fair	21 patients who had an implanted ABS device at a median of 50 months follow-up Patients originally reported in Altomare et al (2001)	*Acticon ABS* N/A	*Acticon ABS* Anal pain=4/21	*Acticon ABS* 4/21 (19%)
(Altomare et al 2001)	Level IV pre-test/post-test case series Quality assessment: Fair	28 patients with severe faecal incontinence	*Acticon ABS* 0/28	*Acticon ABS* Pain=1/28 [b]	*Acticon ABS* 1/28 (7%)

(Casal et al 2004)	Level IV pre-test/post-test case series Quality assessment: Fair	10 patients with severe faecal incontinence	*Acticon ABS* 0/10	*Acticon ABS* Occasional perianal pain=1/10	*Acticon ABS* 1/10 (10%)
(Devesa et al 2002)	Level IV pre-test/post-test case series Quality assessment: Fair	53 consecutive patients with anal incontinence	*Acticon ABS* 0/53	*Acticon ABS* Pain=4/53 [bc]	*Acticon ABS* 4/53 (8%)
(Dodi et al 2000)	Level IV pre-test/post-test case series Quality assessment: Fair	8 women with severe faecal incontinence	*Acticon ABS* Not reported	*Acticon ABS* Not reported	*Acticon ABS* Not reported
(Lehur et al 2002) Note: Some overlap of patients with Lehur et al (1998) and Lehur et al (2000)	Level IV pre-test/post-test case series Quality assessment: Fair	16 patients with severe anal incontinence	*Acticon ABS* 0/16	*Acticon ABS* Painful bowel movements=1/16 [b]	*Acticon ABS* 1/16 (6%)
(Lehur et al 2000) Note: Overlap of four patients with Lehur et al (1998)	Level IV pre-test/post-test case series Quality assessment: Fair	24 patients with severe faecal incontinence	*Acticon ABS* Not reported	*Acticon ABS* Not reported	*Acticon ABS* Not reported
(Lehur et al 1998)	Level IV pre-test/post-test case series Quality assessment: Fair	13 consecutive patients with severe faecal incontinence 4 patients received the Acticon ABS and 9 patients received the AMS 800 urinary sphincter	*Acticon ABS* 0/13	*Acticon ABS* Chronic pain surrounding balloon requiring surgical revision=1/13 [d]	*Acticon ABS* 1/13 (8%)
(Michot et al 2003)	Level IV pre-test/post-test case series Quality assessment: Fair	37 patients with severe faecal incontinence Two groups of patients: Group I=12 patients implanted before October 1996 Group II=25 patients implanted between October 1996 and April 2001	*Acticon ABS* Group I: Perineal pain=1/12 [b] Group II: 0/25	*Acticon ABS* Group I: 0/12 Group II: 0/25	*Acticon ABS* Group I: 1/12 (8%) Group II: 0/25 (0%)
(Ortiz et al 2002)	Level IV pre-test/post-test case	22 patients with severe faecal	*Acticon ABS* 0/22	*Acticon ABS* Perineal pain=3/22	*Acticon ABS* 3/22 (14%)

	series Quality assessment: Fair	incontinence		[b] Two of these patients required explantation	
(Vaizey et al 1998)	Level IV pre-test/post-test case series Quality assessment: Fair	6 females with severe faecal incontinence	*Acticon ABS* 0/6	*Acticon ABS* Pain at cuff site=1/6 [e]	*Acticon ABS* 1/6 (17%)
(O'Brien & Skinner 2000)	Level IV pre-test/post-test case series Quality assessment: Poor	13 patients with severe faecal incontinence	*Acticon ABS* Excessive perineal pain=2/13 [d]	*Acticon ABS* 0/13	*Acticon ABS* 2/13 (15%)
(Savoye et al 2000)	Level IV pre-test/post-test case series Quality assessment: Poor	12 consecutive patients with severe faecal incontinence	*Acticon ABS* Not reported	*Acticon ABS* Not reported	*Acticon ABS* Not reported
(La Torre et al 2004)	Level IV pre-test/post-test case series Quality assessment: Poor	8 patients with severe faecal incontinence, 1 patient with APR	*Acticon ABS* Persistent perianal pain=1/8	*Acticon ABS* 0/8	*Acticon ABS* 1/8 (13%)
(Savoye-Collet et al 2006)	Case report Quality assessment: N/A	61 year old woman with Acticon ABS implanted 6 months previously for severe faecal incontinence	*Acticon ABS* Not reported	*Acticon ABS* Not reported	*Acticon ABS* Not reported
(Benoist et al 2005)	Case report Quality assessment: N/A	25 year old male with high imperforate anus associated with rectourethral fistula	*Acticon ABS* Not reported	*Acticon ABS* Not reported	*Acticon ABS* Not reported

[a] Results of Group I are not reported as they do not meet inclusion criteria for this review; [b] see also Table 9; [c] see also Table 12; [d] see also Table 11; [e] see also Table 8; N/A=not applicable; APR=abdominoperineal resection

Surgical revision

Surgical revision or other surgical procedures following implantation of the Acticon ABS were reported in 14 of 19 studies which met the inclusion criteria (Table 11). The number of surgical procedures performed following implantation of the Acticon ABS was 140 in 116 of 457 patients (25%). Rates of surgical revision ranged from 0 per cent to 49 per cent of patients who received the Acticon ABS.

The comparative studies of Ortiz et al (2003) and da Silva et al (2004) both reported the surgical revision rate for the Acticon ABS compared to dynamic graciloplasty. Ortiz et al (2003) reported revision rates for the Acticon ABS and dynamic graciloplasty as 25 per cent and 13 per cent respectively after a median follow-up of at least 3 years. In contrast, da Silva et al (2004) reported revision rates for the Acticon ABS and dynamic graciloplasty as 9 per cent and 60 per cent respectively. However, in the latter study, the mean follow-up time for the Acticon ABS was considerably shorter than that for dynamic graciloplasty, at 12 months and 38 months respectively.

Wong et al (2002) reported 138 surgeries within the 12 month follow-up as a result of adverse events occurring after implantation of 112 Acticon ABS devices. It is unclear as to how many patients underwent the 138 surgeries. Of these, 73 device related revisions were performed in 51 of 112 patients (46%). The authors believed that the high revision rate due to infection may be controlled by the use of a standardised antibiotic regimen, and provided evidence of a trend indicating this.

Parker et al (2003) also reported a high Acticon ABS revision rate (35%) during a mean follow-up period of 39 months. The authors acknowledged that a learning curve was apparent not only with the initial implantation but also regarding treatment of subsequent complications. As a result, those patients requiring revision surgery often required more than one surgery.

Table 11 Surgical revision and other surgical procedures resulting from implantation of the Acticon ABS for severe faecal incontinence

Study	Study design and quality appraisal	Population	Post-operative revision (number of patients)	Revision during follow-up	Total number of surgical revisions/procedures
(O'Brien et al 2004)	Level II randomised controlled trial Quality assessment: Good	14 patients with severe anal incontinence *Comparator* **Conservative therapy** (n=7)	*Acticon ABS* None reported *Conservative therapy* None reported	*Acticon ABS* None reported *Conservative therapy* None reported	*Acticon ABS* 0/7 (0%) *Conservative therapy* 0/7 (0%)
(Ortiz et al 2003) Note: Overlap between patients with (Ortiz et al 2002)	Level III-2 non-randomised experimental trial Quality assessment: Fair	16 patients with severe faecal incontinence *Comparator* **Dynamic graciloplasty** (n=8)	*Acticon ABS* None reported *Dynamic graciloplasty* None reported	*Acticon ABS* Refilling of cuff=1/8 Rebuttoning cuff at 5 months=1/8 *Dynamic graciloplasty* Gracilis tendon detachment=1/8	*Acticon ABS* 2 revisions in 2/8 (25%) *Dynamic graciloplasty* 1 revision in 1/8 (13%)
(da Silva et al 2004)	Level III-3 non-randomised experimental trial Quality assessment: Fair	16 patients with imperforate anus *Comparator* **Dynamic graciloplasty** (n=5)	*Acticon ABS* None reported *Dynamic graciloplasty* None reported	*Acticon ABS* Control pump dislodged=1/11 *Dynamic graciloplasty* IM electrode displacement=2/5 Surgical debridement of wound infection=1/5 [a]	*Acticon ABS* 1 revision in 1/11 (9%) *Dynamic graciloplasty* 3 revisions in 3/5 (60%)
(Parker et al 2003) Note: 26 patients in Group II were previously reported in Wong et al (2002) (Results of Group I will not be reported as they do not meet inclusion criteria for this review)	Level IV pre-test/post-test case series Quality assessment: Good	47 patients with severe faecal incontinence Group I – 6/10 patients who underwent implantation between 1989 and 1992 [b] Group II – 37 patients who underwent implantation after 1996	*Acticon ABS* Group II: None reported	*Acticon ABS* Group II: 21 revisions in 13/37 patients Number of complications resulting in surgery are expressed as a % of the total number of surgeries: Device replacement=7/21 Cuff replacement=6/21 Pump replacement=3/21 Pump reposition=2/21 Addition of fluid=2/21 Rebuttoning of cuff=1/21	*Acticon ABS* Group II: 21 revisions in 13/37 (35%)
(Wong et al 2002)	Level IV pre-test/post-test case series	115 patients with severe faecal	*Acticon ABS*	*Acticon ABS* 73 device revisions in 51/112 patients	*Acticon ABS* 73 device revisions in 51/112 (46%)

	Quality assessment: Good	incontinence Note: 112 patients were implanted with device		Number of complications resulting in surgery are expressed as a % of the total number of surgeries [c]: Infection=25% Erosion=20% Faecal incontinence=9% Surgical injury=8% Pain=7% Device malfunction=6% Device migration=5% Impaction=2% Other=18%	
(Altomare et al 2004)	Level IV pre-test/post-test case series Quality assessment: Fair	21 patients who had an implanted ABS device at a median of 50 months follow-up Patients originally reported in Altomare et al (2001)	*Acticon ABS* N/A	*Acticon ABS* Replace cuff=4/21 Replace pressure balloon=1/21	*Acticon ABS* 5 revisions in 5/21 (24%)
(Altomare et al 2001)	Level IV pre-test/post-test case series Quality assessment: Fair	28 patients with severe faecal incontinence	*Acticon ABS* Surgical drainage of haematoma=1/28 [d] Perineal wound dehiscence requiring surgical treatment=2/28 [d] Perineal wound dehiscence requiring direct repair=1/28 [d]	*Acticon ABS* Replacement of pressure balloon due to low pressure=1/28 Broken cuff requiring replacement=1/28	*Acticon ABS* 6 revisions in 6/28 (21%)
(Casal et al 2004)	Level IV pre-test/post-test case series Quality assessment: Fair	10 patients with severe faecal incontinence	*Acticon ABS* Surgical cleaning of infection=1/10 [e]	*Acticon ABS* None reported	*Acticon ABS* 1 revisions in 1/10 (10%)
(Devesa et al 2002)	Level IV pre-test/post-test case series Quality assessment: Fair	53 consecutive patients with anal incontinence	*Acticon ABS* None reported	*Acticon ABS* Surgical revision =14/53	*Acticon ABS* 14 revisions in 14/53 (26%)
(Dodi et al 2000)	Level IV pre-test/post-test case series Quality assessment: Fair	8 women with severe faecal incontinence	*Acticon ABS* None reported	*Acticon ABS* None reported	*Acticon ABS* 0/8 (0%)
(Lehur et al	Level IV pre-	16 patients with	*Acticon ABS*	*Acticon ABS*	*Acticon ABS*

2002) Note: Some overlap of patients with Lehur et al (1998) and Lehur et al (2000)	test/post-test case series Quality assessment: Fair	severe anal incontinence	None reported	None reported	0/16 (0%)
(Lehur et al 2000) Note: Overlap of four patients with Lehur et al (1998)	Level IV pre-test/post-test case series Quality assessment: Fair	24 patients with severe faecal incontinence	*Acticon ABS* Pump replacement=1/24	*Acticon ABS* Cuff repositioned=1/24 Cuff rebuttoned=1/24 [ae]	*Acticon ABS* 3 revisions in 3/24 (13%)
(Lehur et al 1998)	Level IV pre-test/post-test case series Quality assessment: Fair	13 consecutive patients with severe faecal incontinence 4 patients received the Acticon ABS and 9 patients received the AMS 800 urinary sphincter	*Acticon ABS* None reported	*Acticon ABS* Surgery for an incisional hernia at temporary stoma site 1 year after implantation=1/13 Control pump repositioned 3 times due to dissatisfaction=1/13 [e] Relocation of balloon due to chronic pain=1/13 [f]	*Acticon ABS* 8 revisions in 6/13 (46%)
(Michot et al 2003)	Level IV pre-test/post-test case series Quality assessment: Fair	37 patients with severe faecal incontinence Two groups of patients: Group I=12 patients implanted before October 1996 Group II=25 patients implanted between October 1996 and April 2001	*Acticon ABS* Group I: Creation of colostomy due to failure of device=1/12 Group II: Rectal wound requiring removal of cuff which was reimplanted=1/25	*Acticon ABS* Group I: None reported Group II: Control pump replaced=3/25 Unexplained dysfunction=1/3 Erosion=2/3 g Balloon relocated=1/25 Tubing relocated=1/25 [g] Rectopexy due to internal rectal procidentia=2/25 [h]	*Acticon ABS* Group I: 1 revision in 1/12 (8%) Group II: 8 revisions in 8/25 (32%)
(Ortiz et al 2002)	Level IV pre-test/post-test case series Quality assessment: Fair	22 patients with severe faecal incontinence	*Acticon ABS* None reported	*Acticon ABS* Migration at 3 months=1/22 Refilling of cuff at 28 months=1/22 Rebuttoning cuff, subsequent explantation and reimplantation=1/22 [e] Exteriorisation at 34 months=1/22	*Acticon ABS* 4 revisions in 4/22 (18%)
(Vaizey et al 1998)	Level IV pre-test/post-test case series Quality	6 females with severe faecal incontinence	*Acticon ABS* None reported	*Acticon ABS* None reported	*Acticon ABS* 0/6 (0%)

	assessment: Fair				
(O'Brien & Skinner 2000)	Level IV pre-test/post-test case series Quality assessment: Poor	13 patients with severe faecal incontinence	*Acticon ABS* Faecal impaction=2/13 [h] Repositioning of cuff=1/13 [f]	*Acticon ABS* Infection=1/13 [a] Repositioning of pump after adherence to scrotal skin=1/13	*Acticon ABS* 5 revisions in 5/13 (38%)
(Savoye et al 2000)	Level IV pre-test/post-test case series Quality assessment: Poor	12 consecutive patients with severe faecal incontinence	*Acticon ABS* None reported	*Acticon ABS* None reported	*Acticon ABS* 0/12 (0%)
(La Torre et al 2004)	Level IV pre-test/post-test case series Quality assessment: Poor	7 patients with severe faecal incontinence, 1 patient with APR	*Acticon ABS* None reported	*Acticon ABS* Temporary removal of cuff due to perianal skin erosion=1/8 [g]	*Acticon ABS* 1 revisions in 1/8 (13%)
(Savoye-Collet et al 2006)	Case report Quality assessment: N/A	61 year old woman with Acticon ABS implanted 6 months previously for severe faecal incontinence	*Acticon ABS* None reported	*Acticon ABS* None reported	*Acticon ABS* 0/1 (0%)
(Benoist et al 2005)	Case report Quality assessment: N/A	25 year old male with high imperforate anus associated with rectourethral fistula	*Acticon ABS* None reported	*Acticon ABS* None reported	*Acticon ABS* 0/1 (0%)

[a] See also Table 8; [b] results of Group I are not reported as they do not meet inclusion criteria for this review; [c] the total number of surgeries (including device related revisions) was 138; [d] see also Table 14; [e] see also Table 9; [f] see also Table 10; [g] see also Table 12; [h] see also Table 13; N/A=not applicable; APR=abdominoperineal resection

Erosion

Erosion is often associated with infection following implantation of the Acticon ABS. However, it is not certain whether erosion follows infection, or if infection is caused by erosion (Wong et al 2002). It must therefore be kept in mind that this may increase the potential for misclassification of outcomes concerning erosion and infection.

Fourteen of 19 studies which met the inclusion criteria for the assessment of safety reported on erosion as an adverse event following implantation of the Acticon ABS (Table 12). Of the 457 patients who received the device, 80 (18%) reported 83 erosion events. Erosion in patients in the included studies ranged from 0 per cent to 43 per cent.

The study conducted by Parker et al (2003) reported that up to 43 per cent of patients in the case series developed erosion after implantation of the Acticon ABS. It was indicated that 12 patients who went on to have the device explanted had done so due to either infection or erosion.

Wong et al (2002) reported erosion in 21 per cent of patients and attributed much of this to the surgical learning curve associated with the implantation procedure. The authors believe that accurate sizing of the cuff and appropriate placement of the pump would result in a reduced rate of erosion. Although this study implanted 112 devices, it was

conducted at multiple centres, and therefore insufficient experience at each centre may have resulted in the notable erosion rate.

Michot et al (2003) reported erosion in 24 per cent of the participating patients. In this study, patients were divided into two groups, the first representing the early experience of the investigators mostly using the modified urinary sphincter, and the second the experience relating to the Acticon ABS. However, despite experience gained with the first group, a similar level of erosion occurred in patients of the second group.

Table 12 Erosion resulting from implantation of the Acticon ABS for severe faecal incontinence

Study	Study design and quality appraisal	Population	Post-operative erosion events	Erosion during follow-up	Total number of erosion events
(O'Brien et al 2004)	Level II randomised controlled trial Quality assessment: Good	14 patients with severe anal incontinence *Comparator* **Conservative therapy** (n=7)	*Acticon ABS* None reported *Conservative therapy* None reported	*Acticon ABS* None reported *Conservative therapy* None reported	*Acticon ABS* 0/7 (0%) *Conservative therapy* 0/7 (0%)
(Ortiz et al 2003) Note: Overlap between patients with (Ortiz et al 2002)	Level III-2 non-randomised experimental trial Quality assessment: Fair	16 patients with severe faecal incontinence *Comparator* **Dynamic graciloplasty** (n=8)	*Acticon ABS* None reported *Dynamic graciloplasty* None reported	*Acticon ABS* Erosion=1/8 [a] *Dynamic graciloplasty* None reported	*Acticon ABS* 1/8 (13%) *Dynamic graciloplasty* 0/8 (0%)
(da Silva et al 2004)	Level III-3 non-randomised experimental trial Quality assessment: Fair	16 patients with imperforate anus *Comparator* **Dynamic graciloplasty** (n=5)	*Acticon ABS* None reported *Dynamic graciloplasty* None reported	*Acticon ABS* None reported *Dynamic graciloplasty* None reported	*Acticon ABS* 0/11 (0%) *Dynamic graciloplasty* 0/5 (0%)
(Parker et al 2003) Note: 26 patients in Group II were previously reported in Wong et al (2002) (Results of Group I will not be reported as they do not meet inclusion criteria for this review)	Level IV pre-test/post-test case series Quality assessment: Good	47 patients with severe faecal incontinence Group I – 6/10 patients who underwent implantation between 1989 and 1992 [b] Group II – 37 patients who underwent implantation after 1996	*Acticon ABS* Group II: Erosion=up to 12/37 [c]	*Acticon ABS* Group II: Erosion=up to 4/37	*Acticon ABS* Group II: Up to 16/37 [f] (43%)
(Wong et al 2002)	Level IV pre-test/post-test case series Quality assessment: Good	115 patients with severe faecal incontinence Note: 112 patients were implanted with device	*Acticon ABS* None reported	*Acticon ABS* 27 erosions in 24/112 patients [d] Cuff erosion=22/27 Pump erosion=4/27 Tubing erosion=1/27	*Acticon ABS* 27 erosions in 24/112 (21%)
(Altomare et al 2004)	Level IV pre-test/post-test case series Quality assessment: Fair	21 patients who had an implanted ABS device at a median of 50 months follow-up Patients originally reported in Altomare et al (2001)	*Acticon ABS* None reported	*Acticon ABS* None reported	*Acticon ABS* 0/21 (0%)

(Altomare et al 2001)	Level IV pre-test/post-test case series Quality assessment: Fair	28 patients with severe faecal incontinence	*Acticon ABS* Erosion=1/28 [a]	*Acticon ABS* Erosion=2/28 [a]	*Acticon ABS* 3/28 (11%)
(Casal et al 2004)	Level IV pre-test/post-test case series Quality assessment: Fair	10 patients with severe faecal incontinence	*Acticon ABS* None reported	*Acticon ABS* Erosion of cuff=1/10 [de]	*Acticon ABS* 1/10 (10%)
(Devesa et al 2002)	Level IV pre-test/post-test case series Quality assessment: Fair	53 consecutive patients with anal incontinence	*Acticon ABS* None reported	*Acticon ABS* Perianal decubitus=5/53 [ad] Erosion of pump=4/53 [ae] Erosion of balloon=1/53 [ae] Skin erosion=1/53 [a] Cuff erosion=1/53 [ae]	*Acticon ABS* 12/53 (23%)
(Dodi et al 2000)	Level IV pre-test/post-test case series Quality assessment: Fair	8 women with severe faecal incontinence	*Acticon ABS* None reported	*Acticon ABS* Erosion of anal mucosa=1/8	*Acticon ABS* 1/8 (13%)
(Lehur et al 2002) Note: Some overlap of patients with Lehur et al (1998) and Lehur et al (2000)	Level IV pre-test/post-test case series Quality assessment: Fair	16 patients with severe anal incontinence	*Acticon ABS* None reported	*Acticon ABS* Erosion of labia=1/16 [a]	*Acticon ABS* 1/16 (6%)
(Lehur et al 2000) Note: Overlap of four patients with Lehur et al (1998)	Level IV pre-test/post-test case series Quality assessment: Fair	24 patients with severe faecal incontinence	*Acticon ABS* Erosion in groin over connecting tubes=1/24 [a]	*Acticon ABS* Perineal erosion=1/24 [a] Ulceration of labia=1/24 [a]	*Acticon ABS* 3/24 (13%)
(Lehur et al 1998)	Level IV pre-test/post-test case series Quality assessment: Fair	13 consecutive patients with severe faecal incontinence 4 patients received the Acticon ABS and 9 patients received the AMS 800 urinary sphincter	*Acticon ABS* None reported	*Acticon ABS* None reported	*Acticon ABS* 0/13 (0%)
(Michot et al 2003)	Level IV pre-test/post-test case series Quality assessment: Fair	37 patients with severe faecal incontinence Two groups of patients: Group I=12 patients implanted before October 1996 Group II=25 patients implanted	*Acticon ABS* Group I: Perineal erosion=3/12 [a] Group II: None reported	*Acticon ABS* Group I: None reported Group II: Erosion of control pump=2/25 [d] Erosion of tubing=1/25 [d] Perineal erosion=3/25 [a]	*Acticon ABS* Group I: 3/12 (25%) Group II: 6/25 (24%) Overall: 9/37 (24%)

		between October 1996 and April 2001			
(Ortiz et al 2002)	Level IV pre-test/post-test case series Quality assessment: Fair	22 patients with severe faecal incontinence	*Acticon ABS* None reported	*Acticon ABS* Erosion and exteriorisation=5/22 [ad]	*Acticon ABS* 5/22 (23%)
(Vaizey et al 1998)	Level IV pre-test/post-test case series Quality assessment: Fair	6 females with severe faecal incontinence	*Acticon ABS* Ulceration through perianal skin due to pressure necrosis=1/6 [a]	*Acticon ABS* None reported	*Acticon ABS* 1/6 (17%)
(O'Brien & Skinner 2000)	Level IV pre-test/post-test case series Quality assessment: Poor	13 patients with severe faecal incontinence	*Acticon ABS* None reported	*Acticon ABS* Erosion of pump=1/13 [ad]	*Acticon ABS* 1/13 (8%)
(Savoye et al 2000)	Level IV pre-test/post-test case series Quality assessment: Poor	12 consecutive patients with severe faecal incontinence	*Acticon ABS* None reported	*Acticon ABS* None reported	*Acticon ABS* 0/12 (0%)
(La Torre et al 2004)	Level IV pre-test/post-test case series Quality assessment: Poor	8 patients with severe faecal incontinence, 1 patient with APR	*Acticon ABS* None reported	*Acticon ABS* Perianal skin erosion requiring temporary removal of cuff=1/8 [d]	*Acticon ABS* 1/8 (13%)
(Savoye-Collet et al 2006)	Case report Quality assessment: N/A	61 year old woman with Acticon ABS implanted 6 months previously for severe faecal incontinence	*Acticon ABS* None reported	*Acticon ABS* None reported	*Acticon ABS* 0/1 (0%)
(Benoist et al 2005)	Case report Quality assessment: N/A	25 year old male with high imperforate anus associated with rectourethral fistula	*Acticon ABS* None reported	*Acticon ABS* None reported	*Acticon ABS* 0/1 (0%)

[a] See also Table 9; [b] results of Group I are not reported as they do not meet inclusion criteria for this review; [c] number of erosion events was reported with infection events and therefore not able to determine exact number; [d] see also Table 11; [e] see also Table 8; APR=abdominoperineal resection

Secondary safety outcomes

Obstructed defecation or faecal impaction

Faecal obstruction or impaction was reported as an adverse event following implantation of the Acticon ABS in 13 of 19 included studies (Table 13). Faecal impaction or obstruction occurred in 95 of 457 patients (21%) receiving the device and rates of these events ranged from 0 per cent to 83 per cent across these studies.

The small study by da Silva et al (2003) reported three of 11 patients (27%) as having faecal impaction requiring digital evacuation. It was noted that these occurrences were in

the post-operative period when patients were learning how to use the Acticon ABS. The group that received dynamic graciloplasty, and were reviewed retrospectively, reported no complications associated with faecal impaction or obstruction.

Faecal impaction and evacuation difficulties were commonly reported adverse events in the study conducted by Wong et al (2002). Twenty seven events of impaction in 21 of 112 patients (19%) were reported, of which three required surgical intervention.

In a poor quality case series (level IV intervention evidence) by Savoye et al (2000), only complications of faecal impaction were described. The small study had a relatively short follow-up period during which six of 12 patients reported faecal impaction as a complication. In one case, inability to open the cuff resulted in severe faecal impaction but no further treatment was reported.

The small study by Vaizey et al (1998), a fair quality uncontrolled case series (level IV intervention evidence), reported that five of six women (83%) had difficulties defecating prior to activation of the device. One of the five women required disimpaction under anaesthesia, while the remaining women were treated successfully with laxatives and enemas. All women in the study subsequently used laxatives or microenemas as required.

Table 13 Obstructed defecation or faecal impaction as a result of implantation of the Acticon ABS

Study	Study design and quality appraisal	Population	Post-operative faecal impaction or obstructed defecation	Faecal impaction or obstructed defecation during follow-up	Total number of events of faecal impaction or obstructed defecation
(O'Brien et al 2004)	Level II randomised, controlled trial Quality assessment: Good	14 patients with severe anal incontinence *Comparator* **Conservative therapy** (n=7)	*Acticon ABS* None reported *Conservative therapy* None reported	*Acticon ABS* None reported *Conservative therapy* None reported	*Acticon ABS* 0/7 (0%) *Conservative therapy* 0/7 (0%)
(Ortiz et al 2003) Note: Overlap between patients with (Ortiz et al 2002)	Level III-2 non-randomised experimental trial Quality assessment: Fair	16 patients with severe faecal incontinence *Comparator* **Dynamic graciloplasty** (n=8)	*Acticon ABS* None reported *Dynamic graciloplasty* None reported	*Acticon ABS* None reported *Dynamic graciloplasty* None reported	*Acticon ABS* 0/8 (0%) *Dynamic graciloplasty* 0/8 (0%)
(da Silva et al 2004)	Level III-3 non-randomised experimental trial Quality assessment: Fair	16 patients with imperforate anus *Comparator* **Dynamic graciloplasty** (n=5)	*Acticon ABS* None reported *Dynamic graciloplasty* None reported	*Acticon ABS* Faecal impaction=3/11 *Dynamic graciloplasty* None reported	*Acticon ABS* 3/11 (27%) *Dynamic graciloplasty* 0/5 (0%)
(Parker et al 2003) Note: 26 patients in Group II were previously reported in Wong et al (2002) (Results of Group I will not be reported as they do not meet inclusion criteria for this review)	Level IV pre-test/post-test case series Quality assessment: Good	47 patients with severe faecal incontinence Group I – 6/10 patients who underwent implantation between 1989 and 1992 [a] Group II – 37 patients who underwent implantation after 1996	*Acticon ABS* Group II: None reported	*Acticon ABS* Group II: Constipation=4/37 [b] Faecal disimpaction=1/37	*Acticon ABS* Group II: 5/37 (14%)
(Wong et al 2002)	Level IV pre-test/post-test case series Quality assessment: Good	115 patients with severe faecal incontinence Note: 112 patients were implanted with device	*Acticon ABS* None reported	*Acticon ABS* Difficult evacuation=10/112 [b] Impaction=21/112 Constipation and impaction=8/112	*Acticon ABS* 39/112 (35%)
(Altomare et al 2004)	Level IV pre-test/post-test case series Quality assessment: Fair	21 patients who had an implanted ABS device at a median of 50 months follow-up Patients originally reported in Altomare et al (2001)	*Acticon ABS* N/A	*Acticon ABS* Untreatable obstructed defecation=1/21 [c] Obstructed defecation=7/21	*Acticon ABS* 8/21 (38%)
(Altomare et	Level IV pre-	28 patients with	*Acticon ABS*	*Acticon ABS*	*Acticon ABS*

al 2001)	test/post-test case series Quality assessment: Fair	severe faecal incontinence	None reported	None reported	0/28 (0%)
(Casal et al 2004)	Level IV pre-test/post-test case series Quality assessment: Fair	10 patients with severe faecal incontinence	*Acticon ABS* None reported	*Acticon ABS* Faecal impaction on two occasions=1/10	*Acticon ABS* 2 episodes of faecal impaction in 1/10 (10%)
(Devesa et al 2002)	Level IV pre-test/post-test case series Quality assessment: Fair	53 consecutive patients with anal incontinence	*Acticon ABS* Faecal impaction=5/53	*Acticon ABS* Faecal impaction=11/53	*Acticon ABS* 16/53 (30%)
(Dodi et al 2000)	Level IV pre-test/post-test case series Quality assessment: Fair	8 women with severe faecal incontinence	*Acticon ABS* None reported	*Acticon ABS* None reported	*Acticon ABS* 0/8 (0%)
(Lehur et al 2002) Note: Some overlap of patients with Lehur et al (1998) and Lehur et al (2000)	Level IV pre-test/post-test case series Quality assessment: Fair	16 patients with severe anal incontinence	*Acticon ABS* None reported	*Acticon ABS* None reported	*Acticon ABS* 0/16 (0%)
(Lehur et al 2000) Note: Overlap of four patients with Lehur et al (1998)	Level IV pre-test/post-test case series Quality assessment: Fair	24 patients with severe faecal incontinence	*Acticon ABS* Defecation difficulties Note: number of patients who had this complication is not stated	*Acticon ABS* Faecal impaction due to inappropriate cuff size=1/24 [c]	*Acticon ABS* At least 1/24 (4%)
(Lehur et al 1998)	Level IV pre-test/post-test case series Quality assessment: Fair	13 consecutive patients with severe faecal incontinence 4 patients received the Acticon ABS and 9 patients received the AMS 800 urinary sphincter	*Acticon ABS* None reported	*Acticon ABS* Faecal impaction=1/13 [c] Impaction after unrelated hospital stay, device deactivated and faecaloma evacuated=1/13	*Acticon ABS* 2/13 (15%)
(Michot et al 2003)	Level IV pre-test/post-test case series Quality assessment: Fair	37 patients with severe faecal incontinence Two groups of patients: Group I=12 patients implanted before October 1996 Group II=25 patients implanted between October 1996 and April 2001	*Acticon ABS* Group I: None reported Group II: None reported	*Acticon ABS* Group I: None reported Group II: Internal rectal procidentia resulting in evacuation difficulties=2/25 [b] Faecaloma formation=2/25	*Acticon ABS* Group I: 0/12 (0%) Group II: 4/25 (16%)
(Ortiz et al 2002)	Level IV pre-test/post-test case	22 patients with severe faecal	*Acticon ABS* None reported	*Acticon ABS* None reported	*Acticon ABS* 0/22 (0%)

	series Quality assessment: Fair	incontinence			
(Vaizey et al 1998)	Level IV pre-test/post-test case series Quality assessment: Fair	6 females with severe faecal incontinence	*Acticon ABS* Defecation difficulties=5/6	*Acticon ABS* None reported	*Acticon ABS* 5/6 (83%)
(O'Brien & Skinner 2000)	Level IV pre-test/post-test case series Quality assessment: Poor	13 patients with severe faecal incontinence	*Acticon ABS* Faecal impaction requiring disimpaction under anaesthesia=2/13 [b]	*Acticon ABS* None reported	*Acticon ABS* 2/13 (15%)
(Savoye et al 2000)	Level IV pre-test/post-test case series Quality assessment: Poor	12 consecutive patients with severe faecal incontinence	*Acticon ABS* None reported	*Acticon ABS* Faecal impaction requiring small enemas=5/12 Severe faecal impaction=1/12	*Acticon ABS* 6/12 (50%)
(La Torre et al 2004)	Level IV pre-test/post-test case series Quality assessment: Poor	8 patients with severe faecal incontinence, 1 patient with APR	*Acticon ABS* Obstructed defecation =2/8	*Acticon ABS* None reported	*Acticon ABS* 2/8 (25%)
(Savoye-Collet et al 2006)	Case report Quality assessment: N/A	61 year old woman with Acticon ABS implanted 6 months previously for severe faecal incontinence	*Acticon ABS* None reported	*Acticon ABS* None reported	*Acticon ABS* 0/1 (0%)
(Benoist et al 2005)	Case report Quality assessment: N/A	25 year old male with high imperforate anus associated with rectourethral fistula	*Acticon ABS* None reported	*Acticon ABS* None reported	*Acticon ABS* 0/1 (0%)

[a] Results of Group I are not reported as they do not meet inclusion criteria for this review; [b] see also Table 11; [c] see also Table 9; N/A=not applicable; APR=abdominoperineal resection

Other adverse events

Other adverse events associated with implantation of the Acticon ABS included wound dehiscence, haematoma and failure to achieve implantation of the device (Table 14). Reporting of other adverse events occurred in eight of 19 studies included for the assessment of safety.

In the good quality randomised controlled study by O'Brien et al (2004), few complications were reported in the short follow-up time of 6 months. However, the authors did report that there were three patients (43%) who experienced perioperative adverse events in the Acticon ABS group, which required additional treatment or prolonged the hospital stay. The authors reported that two of seven patients in this group had problematic healing of the perineal wound and reasoned that this may have been, in part, attributable to the use of a transverse perineal incision in front of the anus. In their experience, this technique often resulted in prolonged post-operative healing.

Ortiz et al (2003) reported additional adverse events for 50 per cent of patients in both groups – those receiving the Acticon ABS and dynamic graciloplasty. All events were related to wound healing complications.

Wong et al (2002) reported a total of 384 adverse events following implantation of the Acticon ABS. Of these, 223 events have been reported above (Tables 8–13). Therefore, there were an additional 167 adverse events reported in 100 of 115 patients, including six patients for whom the implantation procedure was aborted. Three of these patients went on to have the device implanted at a later date but the remaining three were exited from the study. Procedures were aborted in these three patients due to tissue perforation (1), inability to place cuff due to previous failed graciloplasty (1) and megarectum (1).

Lehur et al (2000) did not report completely on minor complications except to say that patients suffered from limited haematomas and emptying difficulties. Evacuation problems were responsive to laxatives or small enemas. The authors did not indicate the number of patients who suffered these problems. Two patients with wound dehiscence (one healed within a few days, the other required more than a month to heal) had their devices activated later than other patients.

Table 14 Other adverse events occurring as a result of implantation of the Acticon ABS for severe faecal incontinence

Study	Study design and quality appraisal	Population	Peri-operative adverse events	Adverse events during follow-up	Total number of adverse events
(O'Brien et al 2004)	Level II randomised controlled trial Quality assessment: Good	14 patients with severe anal incontinence *Comparator* **Conservative therapy** (n=7)	*Acticon ABS* Failure to heal of perineal wound resulting in explantation=1/7 [a] Delayed healing of perineal wound=1/7 Difficulty in learning to defecate through narrowed lumen=1/7 *Conservative therapy* None reported	*Acticon ABS* None reported *Conservative therapy* None reported	*Acticon ABS* 3/7 (43%) *Conservative therapy* 0/7 (0%)
(Ortiz et al 2003) Note: Overlap between patients with (Ortiz et al 2002)	Level III-2 non-randomised experimental trial Quality assessment: Fair	16 patients with severe faecal incontinence *Comparator* **Dynamic graciloplasty** (n=8)	*Acticon ABS* Wound healing complications=4/8 *Dynamic graciloplasty* Wound healing complications=4/8 [b]	*Acticon ABS* None reported *Dynamic graciloplasty* None reported	*Acticon ABS* 4/8 (50%) *Dynamic graciloplasty* 4/8 (50%)
(Parker et al 2003) Note: 26 patients in Group II were previously reported in Wong et al (2002) (Results of Group I will not be reported as they do not meet inclusion criteria for this review)	Level IV uncontrolled pre-test/post-test case series Quality assessment: Good	47 patients with severe faecal incontinence Group I – 6/10 patients who underwent implantation between 1989 and 1992 [c] Group II – 37 patients who underwent implantation after 1996	*Acticon ABS* Group II: Failure to implant device=2/37 Due to previous gluteal muscle wrap, cuff unable to encompass anal canal=1/2 Initially had cuff placed but refused to complete implantation. Stoma formation followed=1/2	*Acticon ABS* Group II: None reported	*Acticon ABS* Group II: 2/37 (5%)
(Wong et al 2002)	Level IV uncontrolled pre-test/post-test case series Quality assessment: Good	115 patients with severe faecal incontinence Note: 112 patients were implanted with device	*Acticon ABS* Aborted implantation=6/115 Tissue perforation=4/6 Cuff unable to encircle anal canal due to previous failed dynamic graciloplasty=1/6 Megarectum=1/6 Note: 3/6 went on to be reimplanted,	*Acticon ABS* 161 additional adverse events in 97/112	*Acticon ABS* 167 additional adverse events in 100/115 (87%)

			3/6 were exited from study		
(Altomare et al 2001)	Level IV uncontrolled pre-test/post-test case series Quality assessment: Fair	28 patients with severe faecal incontinence	*Acticon ABS* Haematoma at site of balloon requiring surgical drainage=1/28 [a] Superficial dehiscence of perineal wound=9/28 [a]	*Acticon ABS* None reported	*Acticon ABS* 10/28 (36%)
(Casal et al 2004)	Level IV uncontrolled pre-test/post-test case series Quality assessment: Fair	10 patients with severe faecal incontinence	*Acticon ABS* Superficial dehiscence of perianal wound=2/10 [d] Perianal haematoma=2/10	*Acticon ABS* Cuff had lost water tightness=2/10 [d]	*Acticon ABS* 6/10 (60%)
(Devesa et al 2002)	Level IV uncontrolled pre-test/post-test case series Quality assessment: Fair	53 consecutive patients with anal incontinence	*Acticon ABS* Wound dehiscence=8/53 Haematoma=7/53 Urethral fistula=1/18 [e] Diarrhoea=4/53	*Acticon ABS* System leakage=1/53	*Acticon ABS* 21/53 (40%)
(Ortiz et al 2002)	Level IV uncontrolled pre-test/post-test case series Quality assessment: Fair	22 patients with severe faecal incontinence	*Acticon ABS* Perineal and abdominal haematomas=4/22 Perineal wound dehiscence=3/22	*Acticon ABS* None reported	*Acticon ABS* 7/22 (32%)
(Lehur et al 2000) Note: Overlap of four patients with Lehur et al (1998)	Level IV uncontrolled pre-test/post-test case series Quality assessment: Fair	24 patients with severe faecal incontinence	*Acticon ABS* Haematoma [f] Wound dehiscence=2/24 Leg phlebitis=1/24 Urinary tract infection=5/24	*Acticon ABS* None reported	*Acticon ABS* 8/24 (33%)

[a] See also Table 11; [b] see also Table 8; [c] results of Group I are not reported as they do not meet inclusion criteria for this review; [d] see also Table 9; [e] see also Table 12; [f] number of patients who had this complication is not stated

Summary – Comparative safety of implantation of the Acticon ABS relative to dynamic graciloplasty, conservative therapy or colostomy for adults with severe faecal incontinence

Nineteen studies were identified which reported on complications associated with implantation of the Acticon ABS for the treatment of severe faecal incontinence. Of these, one good quality study compared implantation of the Acticon ABS to conservative therapy in a randomised controlled trial (level II intervention evidence). Two further studies, of fair quality, compared implantation of the Acticon ABS to dynamic graciloplasty, one using concurrent controls and the other using historical controls (level III-2 and III-3 intervention evidence respectively). The remaining studies were uncontrolled case series (level IV intervention evidence) and ranged from good to poor quality. No studies were identified which compared implantation of the

Acticon ABS to colostomy.

The good quality randomised controlled study which compared implantation of the Acticon ABS to conservative therapy in an Australian setting did not report any adverse events relating to the implementation of conservative therapy (O'Brien et al 2004). In contrast, of those patients receiving the Acticon ABS, 43 per cent (3/7) reported adverse events, of which the majority (2/7) were related to prolonged wound healing. One of two patients who had problematic wound healing went on to have the device explanted. The major shortcomings of this study are the short follow-up period of 6 months and the small numbers of patients participating. Based on the other studies included, it would be reasonable to assume that a number of adverse events would be reported during an extended follow-up.

Evidence of adverse events following implantation of the Acticon ABS compared to dynamic graciloplasty was limited to two studies. Ortiz et al (2003) and da Silva et al (2004) conducted studies of level III-2 and level III-3 intervention evidence respectively. Both studies indicated that implantation of the Acticon ABS resulted in less infection than dynamic graciloplasty, and that the procedures were similar in the proportion of explantations and reports of pain. Heterogeneous results in terms of surgical revision, erosion and obstructed defecation were reported. While both studies were characterised by small numbers, the study of da Silva et al (2004) was further limited by a follow-up of only 12 months for those receiving the Acticon ABS, and the retrospective review of medical records of patients receiving dynamic graciloplasty.

Infection was a significant adverse event following implantation of the Acticon ABS. Only four studies did not report this event. Of these, one study was of poor quality (Savoye et al 2000), one had small numbers and a short follow-up period (O'Brien et al 2004), another had limited reporting of complications with only explantation reported (Lehur et al 2002), and the final study (Ortiz et al 2003), although with adequate follow-up, had a small number of subjects. In the 15 studies that did report infection, the rate of infection among patients ranged from 4 per cent to 46 per cent.

Explantation was often (in all but three studies) reported as a complication of this procedure, and often followed from infection. Two of three studies were of poor quality (La Torre et al 2004; Savoye et al 2000) and the third (da Silva et al 2004) had small numbers of patients who were followed up for a mean of 12 months, which may not be adequate in order to capture all relevant procedure- and device-related complications. In the studies that reported explantation as a complication of the procedure, rates ranged from 14 per cent to 68 per cent.

Surgical revision, erosion, pain and defecation difficulties were all reported as complications associated with implantation of the Acticon ABS. Rates of adverse events varied among the studies and appear to be affected by quality of the study and length of follow-up as much as by the nature of the procedure itself.

Is it effective?

Outcomes used to assess the effectiveness of implantation of the Acticon ABS were: change in continence, quality of life, functionality of device at end of follow-up and length of hospital stay. Change in continence and quality of life were considered to be the primary outcomes for the assessment of effectiveness.

Studies were included in this assessment of the effectiveness of the Acticon ABS in the treatment of severe faecal incontinence according to the inclusion criteria, defined a priori, in Box 3.

Box 3 Inclusion criteria for identification of studies relevant to an assessment of the effectiveness of implantation of the Acticon ABS in the treatment of severe faecal incontinence

Research question

Is implantation of the Acticon ABS as effective as, or more effective than, dynamic graciloplasty, conservative therapy or colostomy for patients with severe faecal incontinence?

Selection criteria	Inclusion criteria
Population	Post-pubescent patients with clinically determined severe faecal incontinence
Intervention	Implantation of the Acticon ABS
Comparator(s)	Dynamic graciloplasty, conservative therapy or colostomy
Outcomes	Primary outcomes: Continence; incontinence severity scores; quality of life
	Secondary outcomes: Functionality of device; length of hospital stay
Study design	Randomised or non-randomised controlled trials, cohort studies, registers, case series or systematic reviews of these study designs
Search period	1996 – 4/2007
Language	Studies in languages other than English were only translated and included if they represented a higher level of evidence than that available in the English language evidence-base.

The number of studies identified as having met the inclusion criteria for an assessment of effectiveness was 19.

Data from studies have been extracted into tables (Tables 15 to 24) to describe the relevant outcomes, and been ordered in a hierarchical manner according to each study's level of evidence, quality assessment, alphabetical listing and most recent publication date.

As indicated earlier in the assessment of safety, a systematic review published by Mundy et al (2004) reported on the safety and effectiveness associated with implantation of the Acticon ABS. As no comparative studies had been published in relation to the Acticon ABS at the time, it simply reported on effectiveness outcomes relating to this procedure. Unlike Mundy et al (2004), studies which implanted the modified urinary sphincter have not been included in this assessment.

Primary effectiveness outcomes

Incontinence severity scores

Tools used to measure the change in continence varied between studies. To minimise confusion regarding the results, data have been reported in results tables relating to the tool/scale used to measure incontinence severity.

The Cleveland Clinic continence scale incorporates the degree and frequency of incontinence, with impact on lifestyle and hence quality of life (Jorge & Wexner 1993). The questionnaire is simple to use and provides a score between 0 and 20, with 0 indicating complete continence and 20 indicating complete incontinence (see Appendix F).

Nine studies reported change in continence scores after implantation of the Acticon ABS using the Cleveland Clinic continence grading scale (Table 15). It should be noted that, of the studies that reported continence scores, change in continence was only reported in those patients who had retained a functioning device; thus, an intention-to-treat analysis was not conducted. One study compared change in incontinence between patients implanted with the Acticon ABS and patients receiving conservative therapy in a randomised controlled trial (level II intervention evidence) (O'Brien et al 2004). Two other studies compared change in incontinence between implantation of the Acticon ABS and dynamic graciloplasty in non-randomised studies (da Silva et al 2004; Ortiz et al 2003). Among all patients who retained a functioning device at the end of follow-up, improvement in continence scores ranged from 50 per cent to 89 per cent.

The good quality study by O'Brien et al (level II intervention evidence) compared continence scores for those receiving the Acticon ABS and conservative therapy at 6 months follow-up. Improvement in continence was seen in recipients of both the Acticon ABS and conservative therapy after 6 months, with improvements of 75 per cent and 18 per cent respectively. The improvement seen in those who received the Acticon ABS was 4.6 times greater than that among those who received conservative therapy. However, one patient (14%) had the device removed before activation, and it is not clear if the authors conducted an intention-to-treat analysis and incorporated the outcomes of this patient into their results.

Comparative studies of both the Acticon ABS and dynamic graciloplasty reported improvement in continence after implantation of the Acticon ABS (da Silva et al 2004; Ortiz et al 2003). Interestingly, the change in continence of patients who received dynamic graciloplasty was strikingly different between the two studies. Ortiz et al (2003) (level III-2 intervention evidence) reported no improvement in continence in patients who received dynamic graciloplasty. It should be noted that, in this study, there were differences in the baseline incontinence severity scores which may have clinical significance, with the group receiving the Acticon ABS having severity scores 10 per cent less than those receiving dynamic graciloplasty. The study by da Silva et al (2004) (level III-3 intervention evidence) indicated that a statistically significant improvement in continence was seen after receiving both dynamic graciloplasty and the Acticon ABS (46 per cent and 58 per cent respectively).

Lehur et al (1998), in a fair quality case series, reported continence scores at the longest follow-up (mean=2.5 years) following implantation. Thirteen patients were implanted and 11 retained a functioning device at the end of follow-up. These patients reported a

mean improvement of 74 per cent in continence. However, it should be noted that, of the 13 patients with severe faecal incontinence, only four received the Acticon ABS and the remainder received the AMS 800 urinary sphincter.

Table 15 Cleveland Clinic Continence scores associated with implantation of the Acticon ABS for severe faecal incontinence

Study	Study design and quality appraisal	Population	Length of follow-up	Pre-operative score [a]	Post-operative score [a]	Pre-test/post-test difference
(O'Brien et al 2004)	Level II randomised controlled trial Quality assessment: Good	14 patients with severe anal incontinence *Comparator* **Conservative therapy** (n=7)	6 months	*Acticon ABS* (n=7) Mean=19±1.2 *Conservative therapy* (n=7) Mean=17.4±2.3	*Acticon ABS* (n=6) Mean=4.8±4.0 *Conservative therapy* (n=7) Mean=14.3±4.6	*Acticon ABS* 14.2 (75%), p=0.001 [b] *Conservative therapy* 3.1 (18%), p=0.21 [b] *Acticon ABS v conservative therapy* p=0.002 [c]
(Ortiz et al 2003) Note: Overlap between patients with (Ortiz et al 2002)	Level III-2 non-randomised experimental trial Quality assessment: Fair	16 patients with severe faecal incontinence *Comparator* **Dynamic graciloplasty** (n=8)	*Acticon ABS* Median=44 months (interquartile range=13) *Dynamic graciloplasty* Median=39 months (interquartile range=15)	*Acticon ABS* (n=8) Median=16 (6.75) *Dynamic graciloplasty* (n=8) Median =18 (4)	*Acticon ABS* (n=8) Median=8 (14.5) *Dynamic graciloplasty* (n=8) Median =18 (12)	*Acticon ABS* 8 (50%), p=0.018 [d] *Dynamic graciloplasty* 0 (0%), p<0.05 [d] *Acticon ABS v conservative therapy* p=0.029 [c]
(da Silva et al 2004)	Level III-3 non-randomised experimental trial Quality assessment: Fair	16 patients with imperforate anus *Comparator* **Dynamic graciloplasty** (n=5)	Mean=20.3 months (Acticon ABS=12; Dynamic graciloplasty= 38.8)	*Acticon ABS* (n=not reported) Mean=18 *Dynamic graciloplasty* Mean=17.4	*Acticon ABS* (n=not reported) Mean=7.5 *Dynamic graciloplasty* Mean=9.4	*Acticon ABS* 10.5 (58%), p<0.01 [d] *Dynamic graciloplasty* 8 (46%), p=0.06 [d]
(Altomare et al 2001)	Level IV pre-test/post-test case series Quality assessment: Fair	28 patients with severe faecal incontinence	Median=19 months (range=7–41)	*Acticon ABS* (n=14) Median=14.9 (range=11–20)	*Acticon ABS* (n=14) Median=2.6 (range=0–6)	*Acticon ABS* 12.3 (83%), p<0.001 [de]
(Devesa et al 2002)	Level IV pre-test/post-test case series Quality assessment: Fair	53 consecutive patients with anal incontinence	Mean=26.5±14 months (range=7–55)	*Acticon ABS* (n=not reported) Median=17±3 (range=10–20)	*Acticon ABS* (n=not reported) Median=4±3 (range=0–14)	*Acticon ABS* 13 (76%), p<0.001 [d]
(Lehur et al 1998)	Level IV pre-test/post-test case series Quality assessment: Fair	13 consecutive patients with severe faecal incontinence Note: Only 4 patients received the Acticon ABS, remainder received the AMS 800	Mean=30 months	*Acticon ABS* (n=11) Mean=17±1.8 (range=14–20)	*Acticon ABS* (n=11) Mean=4.5±3.4 (range=0–10)	*Acticon ABS* 12.5±3.9 (74%) 95% CI: [9.95, 15.13] p<0.0001
(Ortiz et al 2002)	Level IV pre-test/post-test case series Quality assessment:	22 patients with severe faecal incontinence	Mean=28 months (range=6–48)	*Acticon ABS* Mean=18 (range=14–20)	*Acticon ABS* Mean=4 (range=0–14)	*Acticon ABS* 14 (78%), p<0.001 [f]

	Fair					
(Vaizey et al 1998)	Level IV pre-test/post-test case series Quality assessment: Fair	6 females with severe faecal incontinence	Median=9 months (range=4–12 months)	*Acticon ABS* (n=6) Mean=19.5±0.8 (range=18–20)	*Acticon ABS* (n=6) Mean=4.5±4.9 (range=0–13)	*Acticon ABS* 15±5.3 (77%) 95% CI: [9.44, 20.55] p=0.001
(O'Brien & Skinner 2000)	Level IV pre-test/post-test case series Quality assessment: Poor	13 patients with severe faecal incontinence	Not stated	*Acticon ABS* (n=13) Mean=18.7±1.6	*Acticon ABS* (n=10) Mean=2.1±2.6	*Acticon ABS* 16.6 (89%), p<0.0001

[a] Scale out of a possible 20 where a score of 0 indicates complete continence and a score of 20 indicates complete incontinence; [b] paired t-test; [c] Mann-Whitney U test; ABS=artificial bowel sphincter; [d] author's statistical analysis using Wilcoxon rank sum test; [e] author's statistical analysis using Fisher's exact test; [f] unpaired t-test; AMS=American Medical Systems

The Faecal Incontinence Scoring System (FISS) questionnaire was developed specifically for use in the study by Wong et al (2002) (see Appendix F). The questionnaire, which is self-administered, comprises five questions, of which the first four relate to the frequency and type of incontinence (ie solid, liquid or gas). The fifth question relates to the impact incontinence has on lifestyle. Each response is assigned a numerical value which corresponds with severity and impact. The highest value response from questions one to four is added to the numerical value from question five to calculate the faecal incontinence score.

The FISS questionnaire was used in nine studies including Wong et al (2002) (Table 16). All nine studies were pre-test/post-test case series (level IV intervention evidence) and none performed an intention-to-treat analysis. The range of improvement in continence scores using the FISS was 27 per cent to 95 per cent.

The longest follow-up of recipients was seen in the fair quality study of Altomare et al (2004). Originally reported in 2001 (Altomare et al 2001), these patients were followed up for a median of 50 months (4.1 years), over which time the authors reported an improvement in continence scores of 27 per cent. Interestingly, the original publication by Altomare et al (2001) reported a 94 per cent improvement in continence score at a median of 19 months follow-up, indicating a decline in continence over time.

Parker et al (2003) reported the change in continence at 12 months and at greater than 2 years. The faecal incontinence scores improved dramatically from 43 per cent at 12 months to 77 per cent at least 2 years after implantation. Other studies which measured change in continence over time reported little change until 2 years after implantation.

Table 16 Faecal Incontinence Scoring System scores (FISS) associated with implantation of the Acticon ABS for severe faecal incontinence

Study	Study design and quality appraisal	Population	Length of follow-up	Pre-operative score	Post-operative score	Pre-test/post-test absolute difference
(Parker et al 2003) Note: 26 patients in Group II were previously reported in Wong et al (2002)	Level IV uncontrolled pre-test/post-test case series Quality assessment: Good	47 patients with severe faecal incontinence Group I – 6/10 patients who underwent implantation between 1989 and 1992 [a] Group II – 37 patients who underwent implantation after 1996	Group II: Mean=39 months (range=12–60)	*Acticon ABS* Group II: (n=28) Mean=103 (range=74–120)	*Acticon ABS* Group II: At 12 months: (n=14) Mean=59 (range=0–108) At > 24 months: (n=not reported) Mean=24 (range=1–68)	*Acticon ABS* Group II: At 12 months: 44 (43%), p<0.001 [b] At > 24 months: 79 [c] (77%)
(Wong et al 2002)	Level IV uncontrolled pre-test/post-test case series Quality assessment: Good	115 patients with severe faecal incontinence Note: 112 patients were implanted with device	6, 12 months	*Acticon ABS* (n=101) Mean=106 (range=71–120)	*Acticon ABS* 6 months (n=69) Mean=51 (range=0–108) 12 months (n=61) Mean=48 (range=0–120)	*Acticon ABS* 6 months 55 (52%), p<0.0001 [d] 12 months 58 (55%), p<0.0001 [d]
(Altomare et al 2004)	Level IV uncontrolled pre-test/post-test case series Quality assessment: Fair	21 patients who had an implanted ABS device at a median of 50 months follow-up Patients originally reported in Altomare et al (2001)	Median=50 months	*Acticon ABS* (n=14) Median=94	*Acticon ABS* (n=14) Median=69	*Acticon ABS* 25 (27%) [e]
(Altomare et al 2001)	Level IV uncontrolled pre-test/post-test case series Quality assessment: Fair	28 patients with severe faecal incontinence	Median=19 months (range=7–41)	*Acticon ABS* (n=14) Median=98.5 (range=75–120)	*Acticon ABS* (n=14) Median=5.5 (range=0–49)	*Acticon ABS* 93 (94%), p<0.001 [f]
(Casal et al 2004)	Level IV uncontrolled pre-test/post-test case series Quality assessment: Fair	10 patients with severe faecal incontinence	Mean=29 months (range=9–56)	*Acticon ABS* (n=9) Mean=99.9 (range=83–120)	*Acticon ABS* (n=9) Mean=28.4 (range=0–58)	*Acticon ABS* 71.5 (72%), p<0.001 [d]
(Dodi et al 2000)	Level IV uncontrolled pre-test/post-test case series	8 women with severe faecal incontinence	Mean=10.5 months (range=4–23)	*Acticon ABS* (n=8) Mean=96.2 (range=70–108)	*Acticon ABS* (n=6) Mean=19.4 (range=0–61)	*Acticon ABS* 76.8 (80%), p<0.0001 [d]

	Quality assessment: Fair					
(Lehur et al 2002)	Level IV uncontrolled pre-test/post-test case series Quality assessment: Fair	16 patients with anal incontinence Note: Some overlap of patients with Lehur et al (1998) and Lehur et al (2000)	Mean=25 months (range=7–49)	*Acticon ABS* (n=14) Mean=105±14	*Acticon ABS* 6 months: (n=14) Mean=24±25 12 months: (n=10) Mean=32±34 24 months: (n=5) Mean=32±28 >24 months: (n=6) Mean=23±22	*Acticon ABS* 6 months: 81 (77%), p<0.05 [d] 12 months: 73 (70%), p<0.05 [d] 24 months: 73 (70%), p<0.05 [d] >24 months: 82 (78%), p<0.05 [d]
(Lehur et al 2000)	Level IV, uncontrolled pre-test/post-test case series Quality assessment: Fair	24 patients with severe faecal incontinence	Median=20 months (range=6–35)	*Acticon ABS* (n=24) Median=106±13 [g]	*Acticon ABS* 6 months: (n=23) Median=19±32 12 months: (n=17) Median=25±29 End of follow-up: (n=20) Median=25±25	*Acticon ABS* 6 months: 87 (82%), p<0.0001 [f] 12 months: 81 (76%), p<0.0001 [f] End of follow-up: 81 (76%), p<0.0001 [f]
(La Torre et al 2004)	Level IV uncontrolled pre-test/post-test case series Quality assessment: Poor	8 patients with severe faecal incontinence, 1 patient with APR	Mean=26.3 months (range=3–40)	*Acticon ABS* (n=5) Mean=95	*Acticon ABS* (n=5) Mean=5	*Acticon ABS* 90 (95%), p<0.001 [c]

[a] Results of Group I are not reported as they do not meet inclusion criteria for this review; [b] author's statistical analysis using Wilcoxon's rank-sum test; [c] method of statistical analysis not reported; [d] author's statistical analysis using paired t-test; [e] use of statistical analysis not reported; [f] author's statistical analysis using Fisher's exact test and Wilcoxon's rank-sum test; [g] standard deviation must refer to a mean value not reported

Poor reporting of the change in continence following implantation of the Acticon ABS was seen in the studies by Michot et al (2003) and Savoye et al (2000). The study by Michot et al (2003) reported the incontinence severity of 19 of 37 patients according to a simple scoring system whereby the patients were graded according to the degree of incontinence that they suffered. A patient with complete continence to liquid and solid was given a grade of 'A' whereas a patient who was incontinent to gas and liquid was given a grade of 'C' (Table 17). Use of this assessment tool is problematic as no definition of incontinence (eg more than once per week, at least once per month or daily) has been provided by the authors. Similarly, in the study by Savoye et al (2000), no validated scoring system was used to assess the change in continence after implantation of the Acticon ABS. As a result, comparison with change in continence seen in other studies is not possible.

Table 17 Continence of patients without use of a validated scoring method

Study	Study design and quality appraisal	Population	Pre-operative continence	Post-operative continence
(Michot et al 2003)	Level IV pre-test/post-test case series Quality assessment: Fair	37 patients with severe faecal incontinence	Normal continence=0 Incontinent for gas=0 Incontinent for gas and liquid stools=0 Complete incontinence=19	Normal continence=12 Incontinent for gas=3 Incontinent for gas and liquid stools=4 Complete incontinence=0
(Savoye et al 2000)	Level IV pre-test/post-test case series Quality assessment: Poor	12 consecutive patients with severe faecal incontinence	Incontinence to liquid and solid stools=12	Continence for solid stools=12 Continence for solid and liquid stools=8 Permanent or intermittent incontinence to gas=5

Quality of life

The Faecal Incontinence Quality of Life Scale (FIQOL) proposed by Rockwood et al (2000) is a 39-item condition-specific questionnaire consisting of four subscales (lifestyle, coping/behaviour, depression/self-perception and embarrassment).

Four studies reported change in quality of life after implantation of the Acticon ABS using the FIQOL scale (Table 18). Improvement in quality of life scores ranged from 44 per cent to 70 per cent. The longest follow-up period involved in these assessments was in the poor-quality study of La Torre (level IV intervention evidence), which assessed change after 2 years. It should be noted that, in the study by O'Brien et al (2004), the quality of life scores were reported as the percentage of the optimal outcome. In comparison, the other studies reported the scores as a percentage of the maximal score, which also indicated the greatest reduction in quality of life.

The randomised controlled trial published by O'Brien et al (2004) (level II intervention evidence), comparing implantation of the Acticon ABS with conservative therapy, reported a three-fold improvement in quality of life 6 months after implantation compared to conservative therapy (44% versus 12% respectively).

The remaining studies, level IV intervention evidence, all reported an improvement in quality of life which ranged between 57 per cent and 70 per cent.

Table 18 Faecal incontinence quality of life (FIQOL) scale [a] scores associated with implantation of the Acticon ABS for severe faecal incontinence

Study	Study design and quality appraisal	Population	Duration of follow-up	Pre-operative score	Post-operative score	Pre-test/post-test absolute difference
(O'Brien et al 2004)	Level II randomised controlled trial Quality assessment: Good	14 patients with severe anal incontinence *Comparator* **Conservative therapy**	6 months	*Acticon ABS* (n=7) Mean=38.8±6% *Conservative therapy* (n=7) Mean=42.5±22%	*Acticon ABS* (n=not reported) Mean=82.7±14% *Conservative therapy* (n=7) Mean=54.7±26%	*Acticon ABS* 44.4%, p=0.003 [d] *Conservative therapy* 12.2%, p=0.25 [d] *Acticon ABS v conservative therapy* p=0.04 [e]
(Altomare et al 2001)	Level IV pre-test/post-test case series Quality assessment: Fair	28 patients with severe faecal incontinence	Median=19 m onths	*Acticon ABS* (n=14) Median=65%	*Acticon ABS* (n=14) Median=8%	*Acticon ABS* 57%, p<0.001 [bc]
(La Torre et al 2004)	Level IV pre-test/post-test case series Quality assessment: Poor	8 patients with severe faecal incontinence, 1 patient with APR	Mean=26.3 m onths (range=3–40)	*Acticon ABS* (n=6) Mean=94/114 (82%) (range=75–103)	*Acticon ABS* At 9 months (n=6) Mean=14/114 (12%) (range=0–20)	*Acticon ABS* 80 (70%) [95% CI: 75.7, 85.2] p<0.0001
(O'Brien & Skinner 2000)	Level IV pre-test/post-test case series Quality assessment: Poor	13 patients with severe faecal incontinence	Not reported	*Acticon ABS* (n=13) 77±16%	*Acticon ABS* (n=10) 12±19%	*Acticon ABS* 65%

[a] Rockwood et al 2000; [b] Wilcoxon's rank sum test; [c] Fisher's exact test; [d] paired t-test; [e] unpaired t-test

The modified FIQOL was developed and first used in the study by Wong et al (2002). It is a 29-item self-administered questionnaire which, like the FIQOL scale, assesses impact on lifestyle, coping/behaviour, depression/self-perception and embarrassment.

Of the five studies that reported change in quality of life using this scale, all indicated an improvement following implantation of the Acticon ABS (Table 19). However, only two actually reported the mean scores for this assessment.

Da Silva et al (2004) (level III-3 intervention evidence), without reporting individual or mean data, indicated that there was an increase in all four subscales of the questionnaire for both the Acticon ABS and dynamic graciloplasty. The improvement following implantation of the Acticon ABS was reported to be statistically significant, unlike that reported for dynamic graciloplasty.

Parker et al (2003) (level IV intervention evidence) also reported the use of the modified Rockwood scale. Again, without providing individual or summary data, the authors indicated that there was a significant difference at 12 months post-activation in all

subscales of lifestyle, coping, depression and embarrassment ($p=0.002$, $p<0.001$, $p=0.01$, $p=0.001$ respectively, Wilcoxon's rank-sum test).

Devesa et al (2002) reported a statistically significant improvement in quality of life scores in 25 of 53 (47%) patients implanted. Patients whose scores were not included were those with the cuff explanted (19%), those from other countries (26%), those who could not attend the interview (6%) and one (2%) missing after discharge. This may have introduced bias into the assessment of quality of life, as it would not be unreasonable to expect that patients from other countries may have a different quality of life due to different lifestyles, levels of care and social perceptions. The authors have not indicated in which countries the other 14 participating institutions were located. Another potential source of information bias comes from the assessment of quality of life being conducted by personal interview rather than self-administration of the questionnaire.

Table 19 Faecal incontinence quality of life scale scores associated with implantation of the Acticon ABS for severe faecal incontinence using the modified FIQOL scale

Study	Study design and quality appraisal	Population	Duration of follow-up	Pre-operative score (mean±SD [c])	Post-operative score	Pre-test/post-test change
(da Silva et al 2004)	Level III-3 non-randomised experimental trial Quality assessment: Fair	16 patients with imperforate anus *Comparator* **Dynamic graciloplasty** (n=5)	Mean=20.3 months (Acticon ABS=12; Dynamic graciloplasty=38.8)	*Acticon ABS* Scores not reported *Dynamic graciloplasty* Scores not reported	*Acticon ABS* Scores not reported *Dynamic graciloplasty* Scores not reported	*Acticon ABS* Lifestyle and depression/behaviour p=0.02 [a] Coping/behaviour and embarrassment p=0.03 [a] *Dynamic graciloplasty* Lifestyle and depression/behaviour p=0.06 [a] Coping/behaviour and embarrassment p=0.05 [a]
(Parker et al 2003) Note: 26 patients in Group II were previously reported in Wong et al (2002)	Level IV uncontrolled pre-test/post-test case series Quality assessment: Good	47 patients with severe faecal incontinence Group I – 6/10 patients who underwent implantation between 1989 and 1992 [b] Group II – 37 patients who underwent implantation after 1996	Group II: Mean=39 months (range=12–60)	*Acticon ABS* Group II: Scores not reported	*Acticon ABS* Group II: Scores not reported	*Acticon ABS* Group II: Lifestyle p=0.002 [a] Coping p<0.001 [a] Depression p=0.01 [a] Embarrassment p=0.001 [a]
(Wong et al 2002)	Level IV uncontrolled pre-test/post-test case series Quality assessment: Good	115 patients with severe faecal incontinence Note: 112 patients were implanted with device	12 months	Scores not reported	Scores not reported	N/A
(Devesa et al 2002)	Level IV uncontrolled pre-test/post-test case series Quality assessment: Fair	53 consecutive patients with anal incontinence	Mean=26.5±14 months (range=7–55)	*Acticon ABS* (n=25) Lifestyle=1.8±0.8 Coping/behaviour=1.3±0.35 Depression/self-perception=1.9±0.8 Embarrassment=1.3±0.5	*Acticon ABS* (n=25) Lifestyle=3.6±0.6 Coping/behaviour=3.2±0.8 Depression/self-perception=3.5±0.7 Embarrassment=3.3±0.7	*Acticon ABS* Lifestyle 1.8 (100%) Coping/behaviour 1.9 (146%) Depression/self-perception 1.6 (84%) Embarrassment 2.0 (154%) p<0.0001 [c]
(Lehur et al 2002)	Level IV uncontrolled	16 patients with anal	Mean=25 months (range=7–49)	*Acticon ABS*	*Acticon ABS*	*Acticon ABS*

	pre-test/post-test case series Quality assessment: Fair	incontinence	(n=16) Lifestyle [d] Mean=45±18% Coping/behaviour [d] Mean=37±11% Depression/self-perception [d] Mean=53±25% Embarrassment [d] Mean=42±21%	(n=not reported) Lifestyle [d] Mean=91±%12 Coping/behaviour [d] Mean=81±15% Depression/self-perception [d] Mean=87±15% Embarrassment [d] Mean=89±14%	Lifestyle [d] 46%, p<0.0001 [e] Coping/behaviour [d] 44%, p<0.0001 [e] Depression/self-perception [d] 34%, p<0.001 [e] Embarrassment [d] 47%, p<0.0001 [e]

[a] Wilcoxon's rank sum test; [b] results of Group I are not reported as they do not meet inclusion criteria for this review; [c] author's analysis using Dunnet's T-test; [d] reported as a percentage of the maximum possible score (100% indicating highest quality of life); [e] paired t-test

The Health Status Questionnaire is a self-administered questionnaire to determine a patient's perception of their own health status and the impact of health on their physical and social functioning (Wong et al 2002). The addition of questions relating to depression resulted in the HSQ version 2.0, which was used in the study by Wong et al (2002). The questionnaire, although not specifically designed for patients with faecal incontinence, is divided into eight domains relating to health perception, physical functioning, role limitations (physical), role limitations (emotional), social functioning, mental health, bodily pain and energy/fatigue. Each scale produces a score out of 100, with 100 indicating ideal function. A total HSQ score is provided when all scores from the eight domains are added together.

The data provided by Wong et al (2002) (level IV intervention evidence) in regard to the HSQ indicated that, of the 44 of 112 (39%) patients who received the device, a statistically significant improvement of 22 per cent was reported 12 months following implantation (Table 20).

Table 20 HSQ [a] scores associated with implantation of the Acticon ABS for severe faecal incontinence

Study	Study design and quality appraisal	Population	Pre-operative score (mean±SD)	Post-operative score at 12 months	Pre-test/post-test absolute difference
(Wong et al 2002)	Level IV uncontrolled pre-test/post-test case series Quality assessment: Good	115 patients with severe faecal incontinence Note: 112 patients were implanted with device	*Acticon ABS* (n=44) Mean =455	*Acticon ABS* (n=44) Mean=553	*Acticon ABS* 98 (22%), p<0.0001 [b]

[a] Health status questionnaire; [b] author's analysis using Dunnet's T-test

The SF-36 is a generic quality of life scale which assesses eight concepts relating to health and allows comparison with other populations (Rockwood 2004). The concepts assessed by this tool are physical functioning, role limitations due to physical health problems, bodily pain, social functioning, general mental health, vitality and general health perceptions. For these measures, a range of scores is possible ranging from 0 (poor) to 100 (excellent). Two studies used this tool to measure change in quality of life after implantation of the Acticon ABS (Table 21).

O'Brien et al (2004) compared the change in SF-36 scores after implantation of the Acticon ABS to the change in score after receiving conservative therapy. The authors reported the scores as a mental component and a physical component. Patients receiving

the Acticon ABS reported a greater improvement in both the physical and mental components of the questionnaire compared to those receiving conservative therapy following treatment. Neither of the two groups reported a statistically significant improvement in quality of life at 6 months follow-up; however, the quality of life status of patients who received the Acticon ABS was significantly better than those who had received conservative therapy ($p<0.05$).

Table 21 SF-36 [a] scores associated with implantation of the Acticon ABS for severe faecal incontinence

Study	Study design and quality appraisal	Population	Length of follow-up	Pre-operative score (median (range)	Post-operative score (median (range)	Pre-test/post-test absolute difference
(O'Brien et al 2004)	Level II randomised controlled trial Quality assessment: Good	14 patients with severe anal incontinence *Comparator* **Conservative therapy**	6 months	*Acticon ABS* Physical component: (n=7) Mean=37±10 Mental component: (n=7) Mean=45±9 *Conservative therapy* (n=7) Physical component: Mean=41.6±13 Mental component: (n=7) Mean=40.3±10	*Acticon ABS* Physical component: (n=not reported) Mean=45±7 Mental component: (n=not reported) Mean=52±4 *Conservative therapy* Physical component: (n=7) Mean=41±11 Mental component: (n=7) Mean=44.4±5	*Acticon ABS* Physical component: 8 (22%), p=0.26 Mental component: 7 (16%), p=0.25 *Conservative therapy* Physical component: 0.6 (1%), p=0.90 Mental component: 4.1 (10%), p=0.27 *Acticon ABS v conservative therapy* Physical component: p=0.43 Mental component: p=0.02
(Vaizey et al 1998)	Level IV pre-test/post-test case series Quality assessment: Fair	6 females with severe faecal incontinence	Median=9 months (range=4–12)	*Acticon ABS* (n=5) Role-emotional 0 (0–100) General health 85 (60–80) Mental health 74 (40–100) Bodily pain 74 (40–100) Physical functioning 70 (45–90) Role-physical 50 (0–100) Social function 50 (25–75) Vitality 45 (40–80)	*Acticon ABS* (n=5) Role-emotional 33 (0–100) General health 77 (57–87) Mental health 72 (60–80) Bodily pain 60 (22–84) Physical functioning 90 (40–100) Role-physical 50 (0–100) Social function 75 (50—100) Vitality 50 (45–85)	*Acticon ABS* Role-emotional 33 [b] General health - 8 [b] Mental health - 2 [b] Bodily pain - 14 [b] Physical functioning 20 [b] Role-physical 0 [b] Social function 25 [b] Vitality 5 [b]

[a] Short-form 36 questionnaire; [b] statistical significance not reported

The Beck Depression Inventory is a validated self-administered questionnaire used to assess attitudes and symptoms related to depression (O'Brien et al 2004). O'Brien et al (2004) used this tool to measure levels of depression in both arms of their randomised controlled trial (level II intervention evidence) (Table 22). The authors reported an

improvement in the group which received the Acticon ABS although this was not of statistical significance; however, the sample size was small. The group which received conservative therapy showed no improvement and, in fact, their depression may have worsened.

Table 22 Quality of life scores according to the Beck Depression Inventory

Study	Study design and quality appraisal	Population	Length of follow-up	Pre-operative score (median (range)	Post-operative score (median (range)	Pre-test/post-test absolute difference
(O'Brien et al 2004)	Level II randomised controlled trial Quality assessment: Good	14 patients with severe anal incontinence *Comparator* **Conservative therapy** (n=7)	6 months	*Acticon ABS* (n=7) Mean=10.9±9.3 *Conservative therapy* (n=7) Mean=7.3±5.4	*Acticon ABS* (n=not reported) Mean=6.8±8.7 *Conservative therapy* (n=7) Mean=9.3±10	*Acticon ABS* 4.1 (38%), p=0.78 [a] *Conservative therapy* -2 (-27%), p=0.38 [a] *Acticon ABS v conservative therapy* p=0.65 [b]

[a] Paired t-test; [b] unpaired t-test

Secondary effectiveness outcomes

Functionality of device

Functionality of device has been defined as the proportion of implanted devices which are activated and functioning at the end of follow-up relative to all implanted devices.

The functionality of the device at the end of follow-up was reported in 16 of 19 studies (Table 23) and ranged from 29 per cent to 100 per cent. The follow-up period ranged from 6 months (O'Brien et al 2004) to over 5 years (Michot et al 2003). It should be noted that, of the nine patients followed up for 5 years, only three had an Acticon ABS implanted.

Ortiz et al (2003) (level III-2 intervention evidence) reported the functionality of both the Acticon ABS and dynamic graciloplasty after a median of 3.6 years and 3.25 years respectively. The Acticon ABS showed greater functionality than dynamic graciloplasty, with 63 per cent of devices functioning compared to 50 per cent of dynamic graciloplasty procedures.

Da Silva et al (2004) (level III-3 intervention evidence) also compared functionality of the Acticon ABS to dynamic graciloplasty. The follow-up period differed greatly between the two groups, with the Acticon ABS group being 12 months and the dynamic graciloplasty group being 39 months (3.25 years). Despite the disparity in follow-up duration, the functionality in both groups was reported to be the same, at 100 per cent.

Another study which had adequate follow-up was conducted by Altomare et al (2004) (level IV intervention evidence). This study followed 21 of 28 patients who were originally reported in Altomare et al (2001) and who had received the Acticon ABS for the treatment of severe faecal incontinence. Functionality of the devices was assessed

after a median of 50 months (4.2 years), after which only six of 21 (29%) patients had a device which remained functioning.

Table 23 Functionality of the device after implantation of the Acticon ABS for severe faecal incontinence

Study	Study design and quality appraisal	Population	Length of follow-up	Functioning devices at end of follow-up
(O'Brien et al 2004)	Level II randomised controlled trial Quality assessment: Good	14 patients with severe anal incontinence *Comparator* **Conservative therapy** (n=7)	6 months	*Acticon ABS* 6/7 (86%) *Conservative therapy* N/A
(Ortiz et al 2003) Note: Overlap between patients with (Ortiz et al 2002)	Level III-2 non-randomised experimental trial Quality assessment: Fair	16 patients with severe faecal incontinence *Comparator* **Dynamic graciloplasty** (n=8)	*Acticon ABS* Median=44 months (interquartile range=13) *Dynamic graciloplasty* Median=39 months (interquartile range=15)	*Acticon ABS* 5/8 (63%) *Dynamic graciloplasty* 4/8 (50%)
(da Silva et al 2004)	Level III-3 non-randomised experimental trial Quality assessment: Fair	16 patients with imperforate anus *Comparator* **Dynamic graciloplasty**(n=5)	Mean=20.3 months (Acticon ABS=12; dynamic graciloplasty=38.8)	*Acticon ABS* 11/11 (100%) *Dynamic graciloplasty* 5/5 (100%)
(Parker et al 2003) Note: 26 patients in Group II were previously reported in Wong et al (2002)	Level IV pre-test/post-test case series Quality assessment: Good	47 patients with severe faecal incontinence Group I – 6/10 patients who underwent implantation between 1989 and 1992 [a] Group II – 37 patients who underwent implantation after 1996	Group II: Mean=39 months (range=12–60)	Group II: 17/35 (49%)
(Wong et al 2002)	Level IV pre-test/post-test case series Quality assessment: Good	115 patients with severe faecal incontinence Note: 112 patients were implanted with device	12 months	75/112 (67%)
(Altomare et al 2004)	Level IV pre-test/post-test case series Quality assessment: Fair	21 patients who had an implanted ABS device at a median of 50 months follow-up Patients originally reported in Altomare et al (2001)	Median=50 months	6/21 (29%)
(Devesa et al 2002)	Level IV pre-test/post-test case series Quality assessment: Fair	53 consecutive patients with anal incontinence	Mean=26.5±14 months (range=7–55)	43/53 (81%)
(Dodi et al 2000)	Level IV pre-test/post-test case series Quality assessment: Fair	8 women with severe faecal incontinence	Median=10.5 months (range=4–23)	6/8 (75%)
(Lehur et al 2002)	Level IV pre-test/post-test case series Quality assessment: Fair	16 patients with severe faecal incontinence	Mean=25 months (range=7–49)	12/16 (75%)
(Lehur et al 2000)	Level IV pre-test/post-test case series Quality assessment: Fair	24 patients with severe faecal incontinence	Median=20 months (range=6–35)	20/24 (83%)
(Lehur et al 1998)	Level IV pre-test/post-test case series Quality assessment: Fair	13 consecutive patients with severe faecal incontinence Note: Only 4 patients received the Acticon ABS; the remainder received the AMS 800	Mean=30 months	11/13 (85%)

(Michot et al 2003)	Level IV pre-test/post-test case series Quality assessment: Fair	37 patients with severe faecal incontinence Two groups of patients: First group=12 patients implanted before October 1996 Second group=25 patients implanted between October 1996 and April 2001	First group: > 5 years Second group: Mean=34 months (range=7–60)	First group: 5/12 (42%) Second group: 19/25 (76%)
(Ortiz et al 2002)	Level IV pre-test/post-test case series Quality assessment: Fair	22 patients with severe faecal incontinence	Mean=28 months (range=6–48)	15/22 (68%)
(Vaizey et al 1998)	Level IV pre-test/post-test case series Quality assessment: Fair	6 females with severe faecal incontinence	Median=9 months (range=4–12)	5/6 (83%)
(Savoye et al 2000)	Level IV pre-test/post-test case series Quality assessment: Poor–fair	12 consecutive patients with severe faecal incontinence	Mean=16 months (range=4–28)	12/12 (100%)
(O'Brien & Skinner 2000)	Level IV pre-test/post-test case series Quality assessment: Poor	13 patients with severe faecal incontinence	Not stated	10/13 (77%)

[a] Results of Group I are not reported as they do not meet inclusion criteria for this review; AMS=American Medical Systems

Length of hospital stay

Only three studies reported on the length of hospital stay associated with implantation of the Acticon ABS, one of which compared the length of hospital stay with that associated with dynamic graciloplasty and another to conservative therapy (Table 24).

The median hospital stay ranged from 7 days to 9.5 days. As expected, the study by O'Brien et al (2004), comparing implantation of the Acticon ABS to conservative therapy, reported no hospital stay for patients receiving conservative treatment. However, in the study by Ortiz et al (2003), which compared implantation of the Acticon ABS to dynamic graciloplasty, a median hospital stay of 9.5 days and 15 days, respectively, was reported. This would largely be attributable to dynamic graciloplasty being performed as a two stage procedure, with the initial stage transposing the gracilis muscle around the anal canal, and the second stage, after 6 weeks to allow the muscle to recover, implanting the electrodes.

Table 24 Length of hospital stay as a result of operation for management of severe faecal incontinence

Study	Study design and quality appraisal	Population	Length of hospital stay	
			Intervention	Comparator
(O'Brien et al 2004)	Level II randomised controlled trial Quality assessment: Good	14 patients with severe anal incontinence *Comparator* **Conservative therapy**	Median=7 days (range=2–17)	No hospital stay
(Ortiz et al 2003) Note: Overlap between patients with (Ortiz et al 2002)	Level III-2 non-randomised experimental trial Quality assessment: Fair	16 patients with severe faecal incontinence *Comparator* **Dynamic graciloplasty**	Median=10 days (interquartile range=3.5)	Median=15 days (interquartile range=5)
(Lehur et al 2000) Note: Overlap of four patients with Lehur et al (1998)	Level IV uncontrolled pre-test/post-test case series Quality assessment: Fair	24 patients with severe faecal incontinence	Mean=9±4 days	N/A
(Benoist et al 2005)	Case report Quality assessment: N/A	25-year-old male with high imperforate anus associated with rectourethral fistula	*Acticon ABS* 45 days (3-stage surgical procedure)	N/A

N/A=not applicable

Summary – Comparative effectiveness of implantation of the Acticon ABS relative to dynamic graciloplasty, conservative therapy or colostomy for adults with severe faecal incontinence

No studies were identified which compared the effectiveness of implantation of the Acticon ABS compared to colostomy in patients with severe faecal incontinence.

Of the studies that were included in this assessment of effectiveness, one compared the Acticon ABS to conservative treatment of severe faecal incontinence (O'Brien et al 2004). Two other studies compared implantation of the Acticon ABS to dynamic graciloplasty (da Silva et al 2004; Ortiz et al 2003).

All studies included in the assessment of effectiveness were flawed by their failure to analyse data according to an intention to treat. As a result, no indication of incontinence severity or quality of life is given for those patients who were either unable to have the device implanted or subsequently required explantation. These results pertaining to incontinence severity and quality of life are therefore only relevant to patients who have a functioning device, and not to all patients who have undergone implantation of the Acticon ABS.

The small good quality study of O'Brien et al (2004) (level II intervention evidence) compared implantation of the Acticon ABS to conservative therapy. Compared to conservative treatment of severe faecal incontinence, implantation of the Acticon ABS appeared to improve faecal incontinence significantly using the Cleveland Clinic scale (75% and 18% respectively,

p<0.005), as well as quality of life according to the Faecal Incontinence Quality of Life scale (FIQOL). The SF-36, a generic quality of life assessment tool, showed no significant improvement in either the physical or mental component of either group after treatment; however, at the end of follow-up, the group receiving the Acticon ABS had significantly better scores for the mental component of the SF-36 compared to the group receiving conservative treatment (52 and 44 respectively, p<0.05). This cannot be accounted for by a significant difference in baseline scores between the two groups. There was no significant difference seen between the groups after treatment when assessing their level, if any, of depression using the Beck Depression Inventory.

Studies by Ortiz et al (2003) (level III-2 intervention evidence) and da Silva et al (2004) (level III-3 intervention evidence) both compared the effectiveness of implantation of the Acticon ABS to dynamic graciloplasty. Change in continence was measured using the Cleveland Clinic scale in both studies. Ortiz et al (2003) reported a 50 per cent improvement in patients who received the Acticon ABS compared to patients who received dynamic graciloplasty, where there was no improvement in continence. In the study by da Silva et al (2004), improvement in continence was seen in both treatment groups; however, the Acticon ABS group reported a greater improvement compared to dynamic graciloplasty (58 per cent and 46 per cent respectively). The authors did not indicate whether the difference in improvement was statistically significant.

Ortiz et al (2003) did not assess the change in quality of life after intervention with the Acticon ABS or dynamic graciloplasty. However, da Silva et al (2004) used the modified FIQOL scale for this assessment. Although individual or summary scores were not reported, it was indicated that there was a significant improvement in all aspects assessed by the modified FIQOL scale for recipients of the Acticon ABS. For those patients who received dynamic graciloplasty, although improvement was seen in all aspects of the questionnaire, the changes were not of statistical significance.

For the remainder of the studies included in the assessment of effectiveness (level IV intervention evidence), changes in severity of incontinence were measured by a number of scales, making comparison difficult.

Nine studies used the Cleveland Clinic Continence scale to measure changes in continence after implantation of the Acticon ABS. All these studies showed a statistically significant improvement in continence after implantation in patients who retained the device throughout follow-up. The range in improvement was between 50 per cent (Ortiz et al 2003) and 89 per cent (O'Brien & Skinner 2000). The study with the longest follow-up for patients who received this device reported an improvement of 50 per cent after a median follow-up of 44 months.

The Faecal Incontinence Scoring System (FISS) developed by American Medical Systems (AMS) was also used by a number of studies to measure improvement in faecal incontinence. Improvement after implantation ranged between 27 per cent and 95 per cent (Altomare et al 2004; La Torre et al 2004). The longest follow-up for which this measure was reported was a median of 4.2 years (Altomare et al 2004). The improvement in continence after this follow-up was the lowest (27 per cent) reported using this scale.

Quality of life change was measured using a number of scales, both condition-specific and generic, in 10 of 19 studies. All studies, regardless of the assessment tool used, showed a significant improvement following implantation of the Acticon ABS.

Functionality of the device was determined to be the proportion of implanted devices which

remained functioning at the end of follow-up. Sixteen of 19 studies reported this, with functionality ranging from 29 per cent to 100 per cent. It is possible that functionality of the device decreases as the length of follow-up increases, as the two studies with the longest follow-up (4.2 years and >5 years) both reported the smallest proportion of functioning devices (Altomare et al 2004; Michot et al 2003). It is important to point out that the majority of patients in Group I of the study by Michot et al (2003) did not receive the Acticon ABS, but rather the modified urinary sphincter.

Discussion of safety and effectiveness

Is it safe?

Implantation of the Acticon ABS for the treatment of severe faecal incontinence appears to be associated with a number of significant complications including infection, erosion, pain and explantation. Patients often reported more than one adverse event associated with the procedure.

Adverse events related to implantation of the Acticon ABS were reported in all identified studies which assessed the safety associated with this procedure. The nature of the device and the procedure suggest that study quality and design, and in particular the length of follow-up, are important in assessing the associated safety. It is apparent that studies with shorter follow-up were not able to report fully on the adverse events related to the procedure.

In all studies, patients were exited from trials once explantation had occurred. Thus, no further complications which may have arisen from either the implantation or the explantation procedure would have been reported.

Infection is a significant complication associated with implantation of the Acticon ABS, and studies showed up to 46 per cent of patients reporting this event. It was commonly associated with erosion and often led to explantation of the device. Variation in infection rates (0–46%) seen in implanted patients occurred for a number of reasons, including different prophylactic antibiotic regimens employed and the skill and expertise of the surgical team.

No evidence was identified which compared the safety of implanting the Acticon ABS to colostomy.

Evidence comparing implantation of the Acticon ABS to provision of conservative treatment for severe faecal incontinence is minimal. However, the one study identified was conducted in Australia and was of a high level (level II intervention evidence). Shortcomings in the study are related to the short follow-up of patients (6 months) and small numbers of patients involved. While no adverse events were reported for those receiving conservative therapy, implantation of the Acticon ABS resulted in 43 per cent of patients reporting complications related to the procedure, including explantation. It is reasonable to suggest that a longer follow-up period may well have resulted in more complications being reported.

Evidence relating to the comparative safety of implantation of the Acticon ABS and dynamic graciloplasty was limited to two studies (Ortiz et al 2003; da Silva et al 2004), which were of level III-2 and III-3 intervention evidence respectively. Both studies contained only small numbers of patients. The study by da Silva et al (2004) was further limited by relatively short follow-up (12 months) of Acticon ABS patients compared to those who received dynamic graciloplasty, as well as the use of medical records to retrospectively assess the safety of dynamic graciloplasty. Both studies reported less infection resulting from implantation of the Acticon ABS compared to dynamic graciloplasty, but were in disagreement when reporting on the safety of the two procedures in terms of surgical revision, erosion and obstructed defecation. However, in

regard to infection, these results may not be generalisable to the Australian context as both studies performed dynamic graciloplasty as a two- or three-stage procedure. Expert opinion indicates that, in the Australian setting, dynamic graciloplasty is performed in one stage. Therefore, it is reasonable to assume that the infection rates indicated in the literature associated with dynamic graciloplasty may be reduced when performed as a one-stage procedure.

Is it effective?

In this assessment, effectiveness has been determined by considering the improvement in continence and quality of life as primary effectiveness outcomes. Functionality of the device at the end of follow-up has been considered to be a secondary effectiveness outcome.

No evidence was identified which considered the effectiveness of implantation of the Acticon ABS compared to colostomy for treatment of severe faecal incontinence.

The previous MSAC assessment (MSAC 2002) indicated the need for data relating to outcomes assessed in those patients for whom the device had been explanted. Similarly, this assessment of effectiveness of implantation of the Acticon ABS is problematic primarily due to the failure of investigators to analyse according to the intention to treat. No assessment of effectiveness has been made in patients for whom the device has been explanted. As the process of explantation may, in itself, cause further increases in the severity of faecal incontinence, it is essential to assess severity of symptoms and quality of life in these patients.

Comparison between studies of the improvement in continence and quality of life was further complicated due to the use of differing tools to determine these outcomes. In general, of the patients who retained the device after implantation, a significant improvement was seen in both severity of incontinence and quality of life.

Limited comparative evidence is available regarding the relative effectiveness of the Acticon ABS compared with conservative therapy or dynamic graciloplasty. One study, in the Australian setting, provided level II intervention evidence of the effectiveness of the Acticon ABS and conservative therapy (O'Brien et al 2004). However, it was limited by the short-term follow-up after implantation and the small number of patients who participated. In this study, investigators have shown that implantation of the Acticon ABS may result in significantly greater improvement of incontinence over the short term, and in significant improvement in quality of life, compared to conservative therapy.

The use of both condition-specific and generic questionnaires in the study by O'Brien et al (2004) suggests the importance of using the former to assess quality of life. The use of the SF-36 questionnaire did not detect any improvement in the quality of life of either group after treatment, suggesting that the FIQOL, a tool designed specifically for a population suffering faecal incontinence, may be more appropriate.

Two studies compared the effectiveness of the Acticon ABS to dynamic graciloplasty. The assessment suggests that improvement in continence was greater in patients who received the Acticon ABS compared to those who received dynamic graciloplasty. Improvement in the quality of life of patients undergoing these procedures was compared in only one study (level III-2 evidence). Using the modified FIQOL scale,

improvement was seen in both groups; however, a statistically significant improvement was seen only in the group receiving the Acticon ABS.

The body of evidence included in this assessment was appraised according to the NHMRC guidance on clinical practice guideline development (NHMRC 2007). This appraisal considered the evidence-base, in particular the number of studies and their methodological quality; homogeneity of the studies' results; clinical relevance of the primary outcomes for safety and effectiveness; generalisability of the evidence to the population with severe faecal incontinence; and applicability of the evidence to the Australian healthcare system. Table 25 presents the results of the appraisal of the evidence considered in this assessment.

Table 25 Body of evidence assessment matrix

Body of evidence / Component	A Excellent	B Good	C Satisfactory	D Poor
Evidence-base			Level III studies with low risk of bias, or level I or II studies with moderate risk of bias	
Consistency			Some inconsistency reflecting genuine uncertainty around clinical question	
Clinical impact			Moderate	
Generalisability		Population(s) studied in the body of evidence is/are similar to the target population		
Applicability		Applicable to Australian healthcare context with few caveats		

Other relevant considerations

This section provides information that does not fit with the systematic and evidence-based assessment of the safety and effectiveness of implantation of the Acticon ABS for the treatment of severe faecal incontinence but, nevertheless, is important in the consideration of this procedure.

Recently published guidelines for the management of faecal incontinence in adults indicates that a multidisciplinary approach is required, involving pelvic floor muscle training, bowel retraining, specialist dietary advice, biofeedback, electrical stimulation and rectal irrigation (National Institute for Health and Clinical Excellence 2007). However, most people with faecal incontinence suffer from embarrassment and shame, and are often reluctant to discuss their symptoms with their healthcare provider. Poor knowledge regarding management and/or treatment options further reduces the likelihood of such discussions (Madoff et al 2004).

Social and work-related activities are often curtailed for those people with faecal incontinence, resulting in isolation from friends and family (Miner 2004) and impairment of quality of life (Hawes & Ahmad 2006; Madoff et al 2004). There is some evidence to suggest that the severity of incontinence symptoms is significantly associated with the frequency of reported problems relating to usual activities; anxiety and depression; and pain and discomfort (Deutekom et al 2005). For those people with severe faecal incontinence, the importance of treatments which may alleviate or possibly resolve their symptoms should not be underestimated. In fact, when considering the benefits and harms associated with a procedure such as implantation of the Acticon ABS, it may be the patient's preference to undergo such a procedure despite the risks involved.

Some studies have indicated that a learning curve is associated with this procedure despite it being acknowledged as less complex than dynamic graciloplasty (Michot et al 2003; Parker et al 2003; Wong et al 2002). A learning curve can impact on the safety and effectiveness of a procedure, as gaining more skill and knowledge is likely to lead to improvements in health outcomes. This impact is significant, particularly due to the low numbers that would be expected to be performed annually within Australia (less than 10 using the number of procedures of dynamic graciloplasty as an indication) (Medicare Australia 2007a). This may result in difficulties in overcoming the learning curve.

Another aspect which has implications for this procedure is the use of a standardised prophylactic antibiotic regimen. Infection is a frequently reported and significant complication following implantation and also in the longer term. Some studies have indicated use of prophylactic antibodies without providing further details. Other studies, such as that conducted by Wong et al (2002), indicated, after a significant number of infection cases had occurred, that employment of a standardised prophylactic antibiotic regimen showed a strong trend in decreasing the infection rate following implantation. American Medical Systems Inc. have received FDA approval for a label change after a recent clinical study also showed a significant reduction in post-operative infection following use of a new standardised prophylactic antibiotic regimen (American Medical Systems Inc 2007b). This regimen, recommended by an infectious diseases specialist, provides broad coverage against cutaneous and bowel micro-organisms (American Medical Systems Inc 2007b). One of the antibiotics recommended for those patients who do not have an allergy to cephalosporins is cefotetan, which is not currently registered with the Therapeutic Goods Administration (Therapeutic Goods Administration 2007).

The Medicare system of funding in the United States provides funding for certain medical services for people aged 65 years or older, people aged less than 65 years but with certain disabilities, and people with end-stage renal disease. Implantation of the Acticon ABS is covered under the US Medicare system (Centers for Medicare and Medicaid Services 2007; American Medical Systems Inc 2007a).

In summary, there are several issues which should be considered in conjunction with the safety and effectiveness in this assessment of the Acticon ABS. Firstly, the use of an appropriate prophylactic antibiotic regimen is important in minimising the infection rate associated with this procedure. American Medical Systems Inc have recommended a specific antibiotic regimen for this procedure but not all the antibiotics recommended are available for use in Australia (Therapeutic Goods Administration 2007). Secondly, further minimisation of surgical complications will be best achieved by surgeons who have considerable experience with the procedure. Finally, the poor quality of life of people with severe faecal incontinence would result in a proportion of this population opting for implantation of Acticon ABS in spite of the associated complications and the possibility of device removal. Due to the complications associated with implantation, it is essential that prospective patients provide informed consent to the procedure.

What are the economic considerations?

The purpose of economic evaluation is to assist decision-makers in ensuring that society's ultimately scarce resources are allocated to those activities from which we will get the most value. That is, it seeks to enhance economic efficiency. To determine whether further economic evaluation is required, the comparative safety and effectiveness of the intervention must first be determined.

Limited evidence in one study indicates that conservative therapy is safer than implantation of the Acticon ABS although less effective. However, the evidence available is only indicative of the short-term safety and effectiveness. The relative effectiveness of the Acticon ABS procedure would suggest that a cost-effectiveness economic analysis should be considered to compare incremental costs relative to incremental effectiveness of both the Acticon ABS intervention and conservative therapy for the treatment of severe faecal incontinence. However, as there are small numbers of patients involved in this study, a lack of evidence has meant that no such analysis can be conducted.

Comparison between implantation of the Acticon ABS and dynamic graciloplasty using the limited evidence available suggests that the former procedure is more effective in terms of both quality of life and incontinence severity scores. Determination of the comparative safety of this procedure is complicated by equivocal results in regard to surgical revision, erosion and obstructed defecation. In addition, the higher infection rates seen with dynamic graciloplasty may be associated with the multistage procedure used. Similar infection rates would not be expected within the Australian setting, where a single-stage procedure is performed. In terms of explantation and pain, the evidence suggests that implantation of the Acticon ABS is as safe as dynamic graciloplasty. Careful consideration of the higher level evidence and the number of patients involved suggests that surgical revision, erosion and obstructed defecation in the Acticon ABS would be likely to be as safe as, or no worse than, dynamic graciloplasty. Further comparative studies with greater numbers are not anticipated and therefore stronger evidence is unlikely to become available in the future. As a consequence of the overall comparative safety and effectiveness of both implantation of the Acticon ABS and dynamic graciloplasty, a cost-effectiveness analysis is indicated. However, reporting of improvement in continence as a median in one study, as well as the small number of patients involved, means that such an evaluation cannot be conducted.

Although there is a lack of evidence to perform an economic evaluation, a financial analysis of the expenditures associated with implantation of the Acticon ABS for severe faecal incontinence relative to dynamic graciloplasty, colostomy and conservative therapy has been conducted.

Financial incidence analysis

Likely number of procedures in a typical year

With the prevalence of faecal incontinence in Australia ranging between 3 per cent and 16 per cent, only those with severe faecal incontinence would be considered to be eligible for this procedure. Data are not available to indicate the proportion of people with faecal incontinence for whom symptoms are sufficiently severe to be considered for this device. However, the number of people who undergo dynamic graciloplasty may be an adequate indication of the clinical need associated with this procedure. According to Medicare statistics, over the past 5 years, an average of four dynamic graciloplasty procedures have

been performed per year (Medicare Australia 2007a). This correlates well with informed expert opinion, which indicates that at least five implantations of the Acticon ABS were performed within Australia in 2006 (Colorectal Surgical Society of Australia and New Zealand 2007).

Pre-procedural and post-procedural unit costs

The pre-procedural workup to assess anal function is the same for implantation of the Acticon ABS, dynamic graciloplasty and colostomy. Patients undergo pelvic ultrasound, anal manometry and pudendal nerve terminal motor latency. Expert advice has indicated that patients may have, on average, two to three consultations with the specialist prior to the surgical procedure; for the purposes of this assessment, we have assumed that patients will have two consultations. The unit costs involved in the pre-procedural and post-procedural work-up for implantation of the Acticon ABS, dynamic graciloplasty and colostomy are presented in Table 26. It should be noted that if there are any complications following activation of the Acticon ABS or dynamic graciloplasty, a further consultation may be required (MBS item 108).

Table 26 Unit costs of pre- and post-procedural work-up associated with implantation of the Acticon ABS, dynamic graciloplasty and colostomy

Item	Source of estimate	Schedule fee
Consultation with specialist (2)	MBS item 104	$77
	MBS item 105	$39
Pelvic ultrasound	MBS item 55044 (male), 55731 (female)	$111 (male) / $98 (female)
Anal manometry	MBS item 11830	$169
Pudendal nerve terminal motor latency	MBS item 11833	$226
Colonoscopy	MBS item 32090	$302
Post-procedural costs		
Follow-up consult	MBS item 105	$39

Source: Medicare Australia 2007b

For patients receiving conservative therapy, it has been assumed that this treatment would be delivered via a physician whose area of speciality encompasses incontinence. Expert opinion indicates that prior to undergoing conservative treatment, a thorough history and examination would be performed, after which patients are likely to receive an abdominal X-ray and undergo a colonoscopy. The costs associated with this assessment of a private patient are presented in Table 27.

Table 27 Unit costs pre- and post- conservative treatment

Item	Source of estimate	Schedule fee
Consultation with specialist (1)	MBS item 110	$136
Abdominal X-ray	MBS item 58900	$36
Colonoscopy	MBS item 32090	$302
Follow-up consultation	MBS item 116	$68

Source: Medicare Australia 2007b

Unit costs of the procedure and comparators

The unit costs of implantation of the Acticon ABS are presented in Table 28 and include all relevant costs regardless of the agency that bears them.

In performing the financial incidence analysis, it has been assumed that implantation of the Acticon ABS would require an average hospital stay of approximately 5 days. The most relevant AR-DRG category has been chosen to reflect the length of hospital stay for this procedure.

Table 28 Unit costs associated with implantation of the Acticon ABS in a private hospital facility

Item	Estimate	Source of estimate
Cost of Acticon artificial bowel sphincter including cuff, pump, pressure-regulating balloon and accessory package	$15,900 [d]	American Medical Systems Inc [a]
Professional fee – colorectal surgeon	$833	Expert opinion [b] suggests that the professional fee for implantation of the Acticon ABS should be at least that of dynamic graciloplasty. This is thought to be a conservative estimate. MBS item 32209.
Professional fee – surgical assistance	$167	MBS item 51303
Anaesthesia initiation	$72	MBS item 20902
Anaesthesia time units	$143	Expert opinion [b] indicates that the average time of procedure is 120 minutes. MBS item 23083
Hospital facility services [d]	$3,085	Total average charge per AR-DRG V4.2 Private Hospitals Data Bureau; G11A – anal and stomal procedures + CSCC; ALOS 4.16 days [c]
Total	$20,200	

[a] American Medical Systems 2006; [b] MSAC Advisory panel for Application 1107; [c] Department of Health & Ageing 2006; [d] item not covered by Medicare; ALOS=average length of stay

The unit costs for the comparators dynamic graciloplasty, colostomy and conservative therapy are outlined in Table 29, Table 30 and Table 31 respectively.

Table 29 Unit costs associated with dynamic graciloplasty performed in a private hospital facility

Item	Estimate	Source of estimate
Cost of equipment (pulse generator and leads) [a]	$15,000	Expert opinion [b]
Professional fee – colorectal surgeon	$833	MBS item 32209
Professional fee – surgical assistance	$167	MBS item 51303
Anaesthesia initiation	$72	MBS item 20902
Anaesthesia time units	$358	Expert opinion [b] indicates that the average time of procedure is 240 minutes. MBS item 23121
Hospital facility services [c]	$5,734	Total average charge per AR-DRG V4.2 Private Hospitals Data Bureau; G12A – Oth digest sys or pr+cscc/+mal; ALOS 7.40 days [a]
Total	$22,164	

[a] Item not covered by Medicare; [b] MSAC Advisory panel for Application 1107; [c] Department of Health & Ageing 2006; ALOS=average length of stay

The unit costs of colostomy performed in a private hospital (Table 30) reflect the costs associated with the procedure, with the assumption that an end colostomy is performed to prevent continued incontinence to mucous and that the procedure requires 2 hours to perform.

Table 30 Unit costs associated with colostomy performed in a private hospital facility

Item	Estimate	Source of estimate
Professional fee – colorectal surgeon	$931	MBS item 32030
Professional fee – surgical assistance	$186	MBS item 51303
Anaesthesia initiation	$72	MBS item 20902
Anaesthesia time units	$143	Expert opinion [a] indicates that the average time of procedure is approximately 2 hours. MBS item 23083
Hospital facility services [c]	$5,734	Total average charge per AR-DRG V4.2 Private Hospitals Data Bureau; G12A – Oth digest sys or pr+cscc/+mal; ALOS 7.40 days [b]
Total	$7,066	

[a] MSAC Advisory panel for Application 1107; [b] Department of Health & Ageing 2006; [c] item not covered by Medicare; ALOS=average length of stay

The unit costs associated with the delivery of conservative therapy are presented in Table 31. It has been assumed that patients would also be referred to a physiotherapist by their physician for pelvic floor exercises; this may require up to six consultations. However, as private patients, there would be no MBS items associated with physiotherapy consultations and the associated costs would be incurred by the patient or their health insurer.

Table 31 Unit costs associated with conservative treatment of severe faecal incontinence

Item		Estimate	Source of estimate
Physician consultation (2 follow-up consultations)		$136	MBS item 116
Physiotherapy	Initial consultation	$56	Estimate from a private health insurer 3 July 2007
	5 follow-up consultations	$250	
Total		$442	

In summary, the cost per procedure for implantation of the Acticon ABS is $20,200. This estimate includes the cost of purchasing the device and the hospital costs which would be covered by the patient or their health insurer. The cost of dynamic graciloplasty and colostomy per procedure is $22,164 and $7,066 respectively. All of these estimates are for surgical procedures for a private patient in a private hospital facility. Like the Acticon ABS, the estimate for dynamic graciloplasty also reflects the cost of the associated equipment (pulse generator and leads) and hospital costs which would be incurred by the patient or private health insurer. Provision of conservative therapy has been estimated to cost $442.

An additional expenditure which should be kept in mind is the cost of aids such as incontinence pads. Patients receiving the Acticon ABS, dynamic graciloplasty and conservative therapy would all be expected to incur this as a continuing cost, as it is not expected that treatment will ensure complete continence but rather varying degrees of improvement. Such costs will be dependent on the severity of incontinence and the range of improvement after surgery or therapy.

A proportion of patients with severe faecal incontinence will be eligible for a subsidy from the Australian Government to partially cover the cost of continence aids. The Continence Aids Assistance Scheme (CAAS) is available to those who are 5 years of age or older and who have permanent and severe incontinence due to a neurological condition or intellectual impairment; or who have permanent and severe incontinence

and a pensioner concession card. This subsidy can be up to $470 annually on continence products ordered through Intouch, the commercial arm of Spinal Injuries Association Inc (Department of Health and Ageing 2007).

Total costs of procedure

The total costs of providing implantation of the Acticon ABS, dynamic graciloplasty, colostomy or conservative therapy, including the costs of the procedure or treatment and any associated services provided beforehand, are presented in Table 32.

Table 32 Total costs associated with implantation of the Acticon ABS and comparators

Item	Acticon ABS	Dynamic graciloplasty	Colostomy	Conservative therapy
Pre- and post-procedure or treatment costs (male)	$963	$963	$963	$542
Procedure or treatment costs	$20,200	$22,164	$7,066	$442
Total (male)	$21,163	$23,127	$8,029	$984

Cost to the Australian Government

The Australian Government will be responsible for payment of the rebate on items from the Schedule of Medicare Benefits. As implantation of the Acticon ABS will be performed in a hospital facility, the rebate will be 75 per cent of the schedule fee for a private patient in a private hospital facility.

A comparison of MBS item payments, including pre- and post-procedural costs, associated with these procedures or therapy is provided in Table 33.

Table 33 Comparison of MBS item costs for implantation of the Acticon ABS, dynamic graciloplasty, colostomy and conservative therapy

Item	Acticon ABS	Dynamic graciloplasty	Colostomy	Conservative therapy
Pre-procedure				
Consultation	$116	$116	$116	$136
Abdominal X-ray	N/A	N/A	N/A	$36
Pelvic ultrasound	$111(male) $98 (female)	$111(male) $98 (female)	$111(male) $98 (female)	N/A
Anal manometry	$165	$165	$165	N/A
Pudendal nerve terminal motor latency	$221	$221	$221	N/A
Colonoscopy	$302	$302	$302	$302
Procedure/therapy				
Professional fee – surgeon or physician	$833	$833	$931	$136
Surgical assistance	$167	$167	$186	N/A
Anaesthesia	$215	$430	$215	N/A
Post-procedure				
Follow-up consultation	$39	$39	$39	$136
Total (male)	$2,169	$2,384	$2,286	$746

N/A=not applicable

Australian Refined Diagnosis Related Group (AR-DRG) round 8 cost estimates indicate that the public to private patient split for a comparable procedure (anal and stomal procedures) is 70 per cent to 30 per cent. It is therefore reasonable to assume that 30 per cent of Acticon ABS implantations would be performed in the private sector, with the remaining 70 per cent in public hospitals. As it is estimated that there will be approximately four procedures performed annually, approximately one procedure per year would be performed in the private sector and eligible for MBS reimbursement.

The financial implications of subsidising implantation of the Acticon ABS for severe faecal incontinence are calculated by multiplying the estimated cost per procedure by the expected uptake of the procedure in private hospitals. Assuming one procedure would be performed in a private hospital annually, the total annual *saving* from implantation of the Acticon ABS would be between $215 and $117 compared to dynamic graciloplasty and colostomy respectively. Compared to conservative therapy, the total *cost* to the Australian Government would be $1,423 per year.

Cost to private health insurance or patient

Costs that would be incurred by private health insurance and/or the patient are those of the implantable device and the private hospital costs. For those patients who receive conservative treatment, the cost of physiotherapy will be incurred by them or their private health insurer.

Total cost to the States and Territories

Under the Australian Healthcare Agreements, the States and Territories fund in-patient procedures on public patients in public hospitals, as well as public patients in an outpatient facility. By making two assumptions – that the unit costs of the procedure are the same for both public and private patients and that three procedures for severe faecal incontinence will be performed annually – the total cost to the States and Territories of implantation of the Acticon ABS is $63,489. The total cost of performing three procedures of dynamic graciloplasty or colostomy, or providing conservative therapy to three patients, is $69,381, $24,087 or $2,952 respectively.

Total cost to the Australian healthcare system overall

The total cost to the Australian healthcare system incorporates copayments, costs of hospital services and the cost of the device for those procedures performed in the public sector. Therefore, for four implantations of the Acticon ABS (of which three would be performed in the public health system), the total cost is expected to be $65,658. The total cost to the Australian healthcare system for an equivalent four procedures of dynamic graciloplasty, colostomy or provision of conservative therapy would be $71,765, $26,373 or $3,698 respectively. The greater total expenditure associated with implantation of the Acticon ABS and dynamic graciloplasty is a function of the cost of three devices, which would be funded by the public sector. The comparatively small expenditure associated with conservative therapy is largely due to the lack of hospital stay associated with this procedure.

These estimates are likely to under-represent the costs for dynamic graciloplasty and the Acticon ABS due to consequent costs such as explantation, antibiotics, hospitalisations and other downstream costs. Implantation of the Acticon ABS will in all likelihood replace dynamic graciloplasty because it is at least as safe as this current surgical procedure, more effective at restoring continence, and of comparable or lesser cost.

Discussion of economic considerations

Although a cost-effectiveness analysis is warranted in relation to implantation of the Acticon ABS, lack of available and appropriate data has prevented this being conducted.

A financial analysis of the intervention and its comparators has been conducted to indicate the expenditures involved with each procedure from a healthcare system perspective.

The **total** cost of implantation of the Acticon ABS (in the order of $66,000 annually) is approximately $6,000 less than the comparator, dynamic graciloplasty; however, it is more than twice that of colostomy. This estimate of total cost is based on the assumption that four procedures will be performed annually, one in the private sector and the remaining three in the public system.

Financial implications (ie costs eligible for MBS reimbursement) to the Australian Government are similar, per procedure, for implantation of the Acticon ABS, dynamic graciloplasty and colostomy (in the order of $2,000 annually). MBS costs for conservative therapy are nearly half that of the other, invasive, procedures.

The States and Territories will bear the costs of the three procedures which are expected to be performed in the public sector annually (in the order of $63,000 for implantation of the Acticon ABS). This is approximately $6,000 less than the cost of performing the equivalent number of dynamic graciloplasty procedures, and significantly more than colostomy or conservative management.

When considering the expected uptake of the intervention (approximately four procedures per year), the overall impact on the Australian healthcare system is not expected to be significant.

Conclusions

Safety

Significant complications are associated with implantation of the Acticon ABS. A considerable number of patients report infection (0–46%) and erosion (0–43%), which can lead to explantation of the device (0–51%). Due to the close association between erosion and infection, which is often followed by revision or explantation, a number of patients also report multiple complications. As patients were exited from studies after explantation, no evidence is available to indicate any adverse events which may occur after the device has been removed.

No evidence is available to determine the comparative safety of implantation of the Acticon ABS and stoma formation for the treatment of severe faecal incontinence.

Minimal, although high level, evidence indicates that implantation of the Acticon ABS is not as safe as conservative therapy for the treatment of severe faecal incontinence. This evidence is based on short-term follow-up, and may in fact conceal even more complications associated with implantation of the Acticon ABS.

Comparative evidence regarding safety indicates that implantation of the Acticon ABS may be superior to dynamic graciloplasty in terms of infection, and equal to it in regard to explantation. However, the equivocal nature of results in terms of surgical revision, erosion, obstructed defecation and pain make this determination difficult, and further high level evidence with appropriate follow-up would be required to do so. As it is unlikely that such evidence would be obtained, it can be concluded, on the evidence available, that implantation of the Acticon ABS is as safe as dynamic graciloplasty, with the caveat that both procedures are associated with significantly higher rates of complications compared to the conservative management of severe faecal incontinence.

As identified in the section 'Other relevant considerations', an associated learning curve and a requirement for a specialised prophylactic antibiotic regimen are conditions which suggest the availability of this procedure should be limited to centres of excellence or specialisation.

Effectiveness

No evidence has been identified to assess the comparative effectiveness of implantation of the Acticon ABS and colostomy.

Implantation of the Acticon ABS appears to provide significant improvement (27–95%) in the severity of faecal incontinence symptoms in patients who retain the device. The previous MSAC assessment for this intervention highlighted the need for data regarding the change in severity of symptoms in patients for whom the device has been explanted (MSAC 2002); however, no such data have become available.

Without an intention-to treat-analysis, quality of life has only been assessed in patients with a functioning device. Of those patients, the reported improvement in overall quality of life ranged from 44 per cent to 70 per cent using a condition-specific measurement tool.

High level evidence indicates that implantation of the Acticon ABS improves severity of symptoms significantly more than conservative treatment in the short term (≤ 6 months). Further evidence is required to determine the long-term improvement, if any, of incontinence severity. In addition, condition-specific assessment tools indicate a significant improvement in quality of life, compared to conservative treatment, in those patients who retain the device.

Evidence relating to effectiveness in reducing the severity of faecal incontinence symptoms suggests that the Acticon ABS is more effective than dynamic graciloplasty. Limited evidence suggests that quality of life is significantly improved after implantation of the Acticon ABS compared to dynamic graciloplasty. However, further high level evidence studies would need to confirm this.

The long-term success of implanting the device has not been determined and there is some evidence to suggest that its functionality (ranging from 29% to 100% over time periods of 6 months to more than 5 years) decreases over time. It is therefore recommended that studies be conducted to determine the functionality of the Acticon ABS over periods of at least 5 years.

Economic considerations

The improved effectiveness of implantation of the Acticon ABS compared to dynamic graciloplasty and conservative therapy suggests that the cost-effectiveness of the Acticon ABS against the comparators should be investigated. However, a lack of data for both of these comparisons resulted in no formal evaluation being conducted; instead, a financial analysis of the expenditures associated with the procedures was performed.

The expected uptake of this procedure (estimated at four procedures annually) is relatively small and therefore is not expected to result in a significant financial burden to the Australian Government.

The greatest cost associated with this procedure is that of the device itself. Unless performed in the public sector, this cost would be borne by the patient.

It is estimated that only one implantation of the Acticon ABS for severe faecal incontinence will be performed in the private sector annually. This will provide a saving to the Australian Government of between $215 and $117 relative to dynamic graciloplasty and colostomy respectively. Compared to conservative therapy, the Australian Government would incur a cost of $1,423 annually.

Total cost to the Australian healthcare system for this procedure is estimated to be $65,658. This is less than the cost of the equivalent number of dynamic graciloplasty procedures ($71,765) but greater than colostomy ($26,373) or provision of conservative therapy ($3,698).

Recommendation

MSAC has considered the safety, effectiveness and cost-effectiveness for implantation of the Acticon artificial bowel sphincter (ABS) compared with conservative management, colostomy and dynamic graciloplasty.

MSAC finds that there is no evidence comparing the Acticon ABS with colostomy and limited evidence comparing it with conservative management and dynamic graciloplasty.

MSAC finds that the evidence suggests that Acticon ABS implantation is not as safe as conservative management and that it is likely to be at least as safe as dynamic graciloplasty.

MSAC finds that the evidence indicates that the Acticon ABS is more clinically effective than both conservative management and dynamic graciloplasty.

MSAC finds that relative cost effectiveness of the Acticon ABS and the comparators could not be assessed due to lack of data. The comparison of the estimated total costs indicates that the cost to the health system for the Acticon ABS is less than for dynamic graciloplasty.

MSAC recommends that public funding is supported for this procedure.

The Minister for Health and Ageing endorsed this recommendation on 11th April 2008.

Appendix A MSAC terms of reference and membership

MSAC's terms of reference are to:

- advise the Minister for Health and Ageing on the strength of evidence pertaining to new and emerging medical technologies and procedures in relation to their safety, effectiveness and cost-effectiveness and under what circumstances public funding should be supported;
- advise the Minister for Health and Ageing on which new medical technologies and procedures should be funded on an interim basis to allow data to be assembled to determine their safety, effectiveness and cost-effectiveness;
- advise the Minister for Health and Ageing on references related either to new and/or existing medical technologies and procedures; and
- undertake health technology assessment work referred by the Australian Health Ministers' Advisory Council (AHMAC) and report its findings to AHMAC.

The membership of MSAC comprises a mix of clinical expertise covering pathology, nuclear medicine, surgery, specialist medicine and general practice, plus clinical epidemiology and clinical trials, health economics, consumers, and health administration and planning:

Member	Expertise or affiliation
Dr Stephen Blamey (Chair)	general surgery
Associate Professor John Atherton	cardiology
Dr Michael Cleary	emergency medicine
Dr Paul Craft	clinical epidemiology and oncology
Dr Kwun Fong	thoracic medicine
Dr David Gillespie	gastroenterology
Professor Jane Hall	health economics
Professor John Horvath	Chief Medical Officer, Department of Health and Ageing
Associate Professor Terri Jackson	health economics
Professor Brendon Kearney	health administration and planning
Associate Professor Frederick Khafagi	nuclear medicine
Dr Ray Kirk	health research
Dr Ewa Piejko	general practice
Ms Sheila Rimmer	consumer health issues
Professor Ken Thomson	radiology
Dr Mary Turner	Australian Health Ministers' Advisory Council representative
Dr David Wood	orthopaedics

Appendix B Advisory Panel and Evaluators

Advisory panel Application 1107
Placement of artificial bowel sphincters in the management of faecal incontinence

Advisory Panel	
Dr Mary Boyd Turner (Chair) MBBS, DCCH, MHA, MBA, FRACP, FRACMA Director, Medical Administration, Blacktown and Mt Druitt Hospitals, Sydney West Area Health Service	Member of MSAC
Prof Brendon Kearney AM MBBS, FRACP, FRACMA Director of the Institute of Medical and Veterinary Science, Deputy Chair of the MSAC, Chair of the Health Policy Advisory Committee on Technology	Member of MSAC
A/Prof David Fonda MBBS, B Med Sci, MD, FRACP, FAFRM Consultant Geriatrician & Rehabilitation Specialist; Specialist in bladder and bowel control problems	Co-opted expert
Dr David Jarvis MB ChB, FRACGP, BA, B Litt General practitioner (retired); Expert Advisory Council member to the National Continence Management Committee	Royal Australian College of General Practitioners (RACGP) nominee
Dr Matt Rickard MB BS (Hons), MMed (Clin Epi), Dip Paed (NSW), FRACS VMO Colorectal Surgery, Concord Hospital, NSW; Councillor, Colorectal Surgical Society of Australia and New Zealand; Secretary, Section of Colorectal Surgery Executive, Royal Australasian College of Surgeons	Royal Australasian College of Surgeons (RACS) and Colorectal Surgical Society of Australia and New Zealand (CSSANZ) nominee
Ms Sheila Rimmer Hons BSc (Econ), M.A. Political Science Governing committee member, Consumer Health Forum Member, Greater Metropolitan Clinicians Task Force (NSW Health Department)	Consumer Health Forum nominee
Evaluators (Adelaide Health Technology Assessment)	
Ms Liz Buckley, Research Officer	
Ms Tracy Merlin, Manager	
Prof Janet Hiller, Director	

Appendix C Search strategies

Table 34 Search terms used

Area of inquiry	Search terms
Prevalence of faecal incontinence	(((faecal OR fecal OR anal) AND incontinence) OR "fecal incontinence") AND (prevalence OR incidence OR epidemiology OR cross-sectional OR cohort OR registry OR register)
Safety, effectiveness and cost-effectiveness of intervention	((f?ecal OR anal) AND (incontin* OR continen*) OR "faecal incontinence" [MeSH]) AND Anus; Prostheses- and- Implants; artificial; Acticon; cuff; balloon; anal; bowel; sphincter; neosphincter

Table 35 Bibliographic databases used to identify literature on the safety and effectiveness of implantation of the Acticon ABS

Electronic database	Time period
Cinahl	1996 – 04/07
Cochrane Library – including, Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects, the Cochrane Central Register of Controlled Trials (CENTRAL), the Health Technology Assessment Database, the NHS Economic Evaluation Database	1996 – 04/07
Current Contents	1996 – 04/07
Embase.com (including Embase and Medline)	1996 – 04/07
Pre-Medline	1996 – 04/07
ProceedingsFirst	1996 – 04/07
Web of Science – Science Citation Index Expanded	1996 – 04/07
EconLit	1996 – 04/07

Table 36 Other sources of literature

Source	Location
Internet	
NHMRC- National Health and Medical Research Council (Australia)	http://www.health.gov.au/nhmrc/
US Department of Health and Human Services (reports and publications)	http://www.os.dhhs.gov/
New York Academy of Medicine Grey Literature Report	http://www.nyam.org/library/greylit/index.shtml
Trip database	http://www.tripdatabase.com
Current Controlled Trials metaRegister	http://controlled-trials.com/
National Library of Medicine Health Services/Technology Assessment Text	http://text.nlm.nih.gov/
U.K. National Research Register	http://www.update-software.com/National/
Google Scholar	http://scholar.google.com/
Hand Searching (Journals from 2006-2007)	
BJU International	Library or electronic access
American Journal of Proctology, Gastroenterology and Colon & Rectal Surgery	Library or electronic access
Diseases of the Colon & Rectum	Library or electronic access
Scandinavian Journal of Gastroenterology	Library or electronic access

Colorectal Disease	Library or electronic access
International Journal of Colorectal Disease	Library or electronic access
British Journal of Surgery	Library or electronic access
Clinics in Colon & Rectal Surgery	Library or electronic access
Expert Clinicians	
Studies other than those found in regular searches	MSAC Advisory Panel
Pearling	
All included articles had their reference lists searched for additional relevant source material	

Specialty websites

www.continence.org.au	Continence Foundation of Australia Ltd
www.continence.health.gov.au	National Continence Management Strategy (Australia)
www.incontact.org	Incontact
www.continence-foundation.org.uk	UK Continence Foundation
www.aca.uk.com	Association for Continence Advice
www.nafc.org	National Association for Continence
www.bladderbowel.health.gov.au	Bladder and Bowel
www.surgeons.org	Royal Australasian College of Surgeons (Australia)
www.rcseng.ac.uk	Royal College of Surgeons (UK)

Table 37 Health Technology Assessment Agency websites

AUSTRALIA	
Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S)	http://www.surgeons.org/open/asernip-s.htm
Centre for Clinical Effectiveness, Monash University	http://www.med.monash.edu.au/healthservices/cce/evidence/
Centre for Health Economics, Monash University	http://chpe.buseco.monash.edu.au
AUSTRIA	
Institute of Technology Assessment / HTA unit	http://www.oeaw.ac.at/ita/e1-3.htm
CANADA	
Agence d'Evaluation des Technologies et des Modes d'Intervention en Santé (AETMIS)	http://www.aetmis.gouv.qc.ca/en/
Alberta Heritage Foundation for Medical Research (AHFMR)	http://www.ahfmr.ab.ca/publications.html
The Canadian Agency for Drugs And Technologies in Health (CADTH)	http://www.cadth.ca/index.php/en/
Canadian Health Economics Research Association (CHERA/ACRES) – Cabot database	http://www.mycabot.ca
Centre for Health Economics and Policy Analysis (CHEPA), McMaster University	http://www.chepa.org
Centre for Health Services and Policy Research (CHSPR), University of British Columbia	http://www.chspr.ubc.ca
Health Utilities Index (HUI)	http://www.fhs.mcmaster.ca/hug/index.htm
Institute for Clinical and Evaluative Studies (ICES)	http://www.ices.on.ca
Saskatchewan Health Quality Council (Canada)	http://www.hqc.sk.ca
DENMARK	
Danish Centre for Evaluation and Health Technology Assessment (DACEHTA)	www.sst.dk/Planlaegning_og_behandling/Medicinsk_teknologivurdering.aspx?lang=en
Danish Institute for Health Services Research (DSI)	http://www.dsi.dk/engelsk.html
FINLAND	
Finnish Office for Health Technology Assessment (FINOHTA)	http://www.stakes.fi/finohta/e/
FRANCE	
L'Agence Nationale d'Accréditation et d'Evaluation en Santé (ANAES)	http://www.anaes.fr/
GERMANY	
German Institute for Medical Documentation and Information (DIMDI) / HTA	http://www.dimdi.de/static/en
THE NETHERLANDS	
Health Council of the Netherlands Gezondheidsraad	http://www.gr.nl/index.php
Institute for Medical Technology Assessment (Netherlands)	http://www.imta.nl/
NEW ZEALAND	
New Zealand Health Technology Assessment (NZHTA)	http://nzhta.chmeds.ac.nz/
NORWAY	
Norwegian Centre for Health Technology Assessment (SMM)	http://www.oslo.sintef.no/smm/Publications/Engsmdrag/FramesetPublications.htm
SPAIN	
Agencia de Evaluación de Tecnologias Sanitarias, Instituto de Salud "Carlos III"I/Health Technology Assessment Agency (AETS)	http://www.isciii.es/htdocs/en/investigacion/Agencia_quees.jsp
Andalusian Agency for Health Technology Assessment (Spain)	http://www.juntadeandalucia.es/salud/orgdep/AETSA/default.asp?V=EN
Catalan Agency for Health Technology Assessment (CAHTA)	http://www.aatm.es/cgi-bin/frame.pl/ang/pu.html
SWEDEN	

Center for Medical Health Technology Assessment	http://www.cmt.liu.se/English/Engstartsida.html
Swedish Council on Technology Assessment in Health Care (SBU)	http://www.sbu.se/www/index.asp
SWITZERLAND	
Swiss Network on Health Technology Assessment (SNHTA)	http://www.snhta.ch/
UNITED KINGDOM	
National Health Service Health Technology Assessment (UK) / National Coordinating Centre for Health Technology Assessment (NCCHTA)	http://www.hta.nhsweb.nhs.uk/
NHS Quality Improvement Scotland	http://www.nhshealthquality.org/
National Institute for Clinical Excellence (NICE)	http://www.nice.org.uk/index.htm
The European Information Network on New and Changing Health Technologies	http://www.euroscan.bham.ac.uk/
University of York NHS Centre for Reviews and Dissemination (NHS CRD)	http://www.york.ac.uk/inst/crd/
UNITED STATES	
Agency for Healthcare Research and Quality (AHRQ)	http://www.ahrq.gov/clinic/techix.htm
Harvard School of Public Health – Cost-Utility Analysis Registry	http://www.tufts-nemc.org/cearegistry/index.html
Institute for Clinical Systems Improvement (ICSI)	http://www.icsi.org
Minnesota Department of Health (US)	http://www.health.state.mn.us/htac/index.htm
National Information Centre of Health Services Research and Health Care Technology (US)	http://www.nlm.nih.gov/hsrph.html
Oregon Health Resources Commission (US)	http://egov.oregon.gov/DAS/OHPPR/HRC/about_us.shtml
Office of Health Technology Assessment Archive (US)	http://www.wws.princeton.edu/~ota
U.S. Blue Cross/ Blue Shield Association Technology Evaluation Center (Tec)	http://www.bcbs.com/consumertec/index.html
Veteran's Affairs Research and Development Technology Assessment Program (US)	http://www.va.gov/resdev

Appendix D Studies included in the review

Study profiles of included studies on prevalence

Study	Location	Study design	Study population	Prevalence	Definition of faecal incontinence
(Avery et al 2004) Note: Overlap with the population reported in (MacLennan et al 2000)	South Australia, Australia	Cross-sectional survey Face-to-face interview held in the subject's home	4,400 subjects (adults ≥15 years) as part of the 1998 South Australian Health Omnibus survey. A clustered, self-weighting, systematic and multistage area sample of metropolitan and country areas (population ≥ 1,000). Hospitals, hotels and nursing homes were not included 3,010 (70%) were interviewed	Faecal incontinence=87/3010 (3%) Females=4% Males=2% Age-specific prevalence: 15–29 years=1% 30–39 years=2% 40–49 years=4% 50–59 years=3% 60–69 years=6% 70–79 years=4% 80+ years=7%	Faecal incontinence – loss of control of motions
(Boyce et al 2006)	New South Wales, Australia	Cross-sectional survey Postal questionnaire	1,225 subjects (≥18 years) randomly selected from the 1996 electoral roll for the local government area of Penrith 762 (62%) questionnaires were completed and returned	Faecal incontinence=58/762 (8%)	Self-reported faecal incontinence which had been present for at least 12 weeks in the previous year. Note: The 12 weeks need not be consecutive Rome II criteria
(Bytzer et al 2001)	Sydney, Australia	Cross-sectional survey Postal questionnaire	15,000 randomly selected adults on the Australian electoral roll 8,657 (58%) were completed and returned	Diabetic subjects=11/423 (3%) Non-diabetic subjects=65/8185 (1%)	Self-reported faecal incontinence that had been troublesome in the preceding 3 months. A positive answer was recorded if the symptom was reported to occur often or very often
(Chiarelli et al 2003)	Hunter region, New South Wales, Australia	Cross-sectional survey Hospital based interview post-delivery and telephone interview at 12 months post-partum	720 women who experienced a high risk delivery (forceps or ventouse) and/or delivered a high birthweight baby (≥4,000 g) 568 (79%) women completed both immediate and 12 month post-partum interviews	Any faecal incontinence=39/568 (7%) Primiparous=16/298 (5%) Multiparous=23/270 (9%) Incontinent to solid stool=15/568 (3%) Primiparous=7/298 (2%) Multiparous=8/270 (3%) Incontinent to liquid stool=28/568 (5%) Primiparous=12/298 (4%) Multiparous=16/270 (6%)	A response of 'once a month or less'; 'once a week or less'; 'most days'; or 'every day' to either of the following questions: Do you ever: 1. accidentally pass solid bowel motions into your underwear? 2. accidentally pass liquid bowel motions into your underwear?

(Chiarelli et al 2005) Note: Three of four studies included in this study are also included in this review (Kalantar et al 2002; Lam et al 1999; MacLennan et al 2000)	Australia and United States of America	Systematic review	Community-based or cross-sectional studies with greater than 125 participants for which age and sex-specific data could be extracted. Studies used a validated instrument to measure incontinence	Overall faecal incontinence=5% Males=5% <30 yrs=3% 30–39 yrs=8% 40–49 yrs=7% 50–59 yrs=11% 60–69 yrs=10% 70–79 yrs=12% 80+ yrs=23% Females=5% <30 yrs=2% 30–39 yrs=5% 40–49 yrs=8% 50–59 yrs=11% 60–69 yrs=14% 70–79 yrs=11% 80+ yrs=16%	Varied according to individual study
(Ho et al 2005)	North Queensland, Australia	Consecutive case series Self-administered questionnaire	451 consecutive patients attending gynaecology and colorectal clinics at The Townsville Hospital between 31 January and 12 June 2003 Males:females=77:356 435 (96%) consecutive eligible patients participated in the survey	Faecal incontinence=90/435 (21%)	Accidental soiling of clothes or underclothes with faeces
(Kalantar et al 2002)	Sydney, Australia	Cross-sectional survey Postal questionnaire	990 randomly selected subjects from the electoral roll in western Sydney 651 (66%) questionnaires were completed and returned	Total faecal incontinence=72/642 (11%) Females=41/353 (12%) Males=31/286 (11%) Liquid faecal incontinence=58/642 (9%) Females=31/353 (9%) Males=27/286 (9%) Solid faecal incontinence=13/642 (2%) Females=4/353 (1%) Males = 9/286 (3%)	Involuntary loss of anal sphincteric control that led to unwanted release of liquid or solid faeces (not flatus) at an inappropriate time or in an inappropriate place in the previous 12 months
(Lam et al 1999)	Sydney, Australia	Cross-sectional survey Postal questionnaire	955 randomly selected subjects from the Southern Sydney electoral roll 618 (65%) questionnaires were completed and returned. Of the responders, M=259; F=359 with a mean age of 55.3 years and 55.7 years respectively	Total faecal incontinence= 92/618 (15%) >1/week=2% <1/week=8% Females = 40/359 (11%) >65 years=14% <65 years=10% Males = 52/259 (20%) >65 years=N/A <65 years= N/A	Positive answer to at least two of three questions which incorporated stool leakage, wearing a pad for faecal soiling or >25% incontinence of flatus

(Lynch et al 2001)	Canterbury, New Zealand	Cross-sectional survey Postal questionnaire	1,500 subjects randomly selected from the electoral roll in the Canterbury region 717 (48%) completed and returned the questionnaire. Of the responders, 388 (54%) were male and 329 (46%) were female	Faecal incontinence =118/717 (16%) Females=51/329 (16%) Males=67/388 (17%)	A score ≥ 3 using the Cleveland Clinic incontinence scoring system
(MacLennan et al 2000) Note: Overlap with the population reported in (Avery et al 2004)	South Australia, Australia	Cross-sectional survey Face-to-face interview held in the subject's home	4,400 subjects (adults ≥15 years) as part of the 1998 South Australian Health Omnibus survey. A clustered, self-weighting, systematic and multistage area sample of metropolitan and country areas (populations ≥ 1,000). Hospitals, hotels and nursing homes were not included 3,010 (70%) were interviewed	Faecal incontinence =87/3010 (3%) Females=54/1546 (3%) Males=33/1464 (2%)	Faecal incontinence – loss of control of motions within the last year
(Ng et al 2005)	Sydney, Australia	Cross-sectional survey Postal questionnaire	180 patients randomly selected from the SCI database at the Royal North Shore Hospital 110 (61%) questionnaires completed and returned	Faecal incontinence=45/110 (41%)	Recurrent uncontrolled passage of faecal material for at least 1 month, in an individual with a developmental age of at least 4 years, associated with: 1. faecal impaction; 2. diarrhoea; or 3. non-structural anal sphincter dysfunction
(Talley et al 2002)	Australia	Prospective cohort Postal questionnaire at baseline and then 3 years later	1,800 subjects randomly selected from Diabetes Australia mailing list 540 (50%) questionnaires completed and returned	Faecal incontinence: At baseline=39/540 (7%) At 3 years=39/540 (7%)	Rome I criteria
(White et al 2000)	Adelaide, Australia	Consecutive series Face-to-face interview	71 patients attending the Royal Adelaide Hospital Adult CF unit	Faecal incontinence=1/71 (1%) Females=0/29 (0%) Males=1/42(2%)	Having ever leaked faeces
(Yeoh et al 2004)	Adelaide, Australia	Consecutive series Questionnaire	38 patients after completion of radiotherapy for prostate cancer	Faecal incontinence: Pre-RT=2/38 (5%) 4–6 week post-RT=15/38 (39%) 1 year post-RT=11/38 (29%) 2 year post-RT=10/38 (26%)	Not stated

FGID=functional gastrointestinal disorders; SCI=spinal cord injury; CF=cystic fibrosis; RT=radiotherapy

Study profiles of included studies on safety and effectiveness

Study and location	Level of evidence and quality assessment	Study design	Study population	Intervention	Inclusion/exclusion criteria	Outcomes assessed	Duration of follow-up
(Altomare et al 2001) Padua, Bari, Rome, Naples; Italy	IV Quality assessment: Fair	Pre-test/post-test case series	28 female patients with severe faecal incontinence Mean age=58 years (range=35–79) Median duration of faecal incontinence=9 years (range=1–49)	Implantation of Acticon ABS	*Inclusion* Not stated *Exclusion* Not stated	*Safety* Adverse events post-operatively and during follow-up *Effectiveness* Primary: CCCS, AMS incontinence score and AMS QOL	Median=19 months (range=7–41)
(Altomare et al 2004) Padua, Bari, Rome, Naples; Italy Note: Patients originally reported in Altomare et al (2001)	IV Quality assessment: Fair	Pre-test/post-test case series	18 patients who had an implanted Acticon ABS device at a median of 50 months follow-up Note: Three patients were not available for further long-term evaluation but it was indicated that they still had a device implanted	Implantation of Acticon ABS	*Inclusion* Not stated *Exclusion* Not stated	*Safety* Adverse events during follow-up *Effectiveness* Primary: Continence Secondary: Functionality of device	Median=50 months
(Benoist et al 2005)	N/A Quality assessment: N/A	Case report	25 year old male with high imperforate anus associated with rectourethral fistula Previous procedures: Combined pull-through procedure with perineal colostomy and posterior sagittal anorectoplasty Small bowel resection with ileocecal resection and restorative end-to-side jejunotransverser anastomosis	Implantation of Acticon ABS	*Inclusion* N/A *Exclusion* N/A	*Safety* Adverse events during follow-up	2 years

(Casal et al 2004) Spain	IV Quality assessment: Fair	Pre-test/post-test case series	10 patients with severe faecal incontinence 2 males, 8 females Mean age=56 years (range=47–67) Mean duration of faecal incontinence=151 months (range=8–360) Aetiology of faecal incontinence: Obstetric injury=4 Neuropathy=3 Iatrogenic sphincter injury=3	Implantation of Acticon ABS	*Inclusion* Not stated *Exclusion* Not stated	*Safety* Adverse events during follow-up *Effectiveness* Primary: Continence scores (AMS) and anorectal manometry	Mean=29 months (range=9–56)
(da Silva et al 2004) Cleveland Clinic, Florida, USA and University of São Paulo, Brazil	III-3 Quality assessment: Fair	Non-randomised, experimental trial Prospective (8 patients with Acticon ABS) Retrospective (3 patients with Acticon ABS, 5 patients with DGP)	16 patients with imperforate anus 11 males, 5 females Mean age=25 years (range=15–45) *Acticon ABS* 11 patients *Dynamic graciloplasty* 5 patients	Implantation of Acticon ABS or Dynamic graciloplasty	*Inclusion* All patients receiving either Acticon ABS or dynamic graciloplasty between February 1995 and December 2000 *Exclusion* Not stated	*Safety* Adverse events post-operatively and during follow-up *Effectiveness* Primary: CCCS and QOL Secondary: Functionality of device	Mean=20.3 months (Acticon ABS=12; Dynamic graciloplasty=38.8)
(Devesa et al 2002) Madrid, Spain and other countries	IV Quality assessment: Fair	Pre-test/post-test case series	53 consecutive patients with anal incontinence 18 males, 35 females Median age=46 years (range=16–76) Aetiology of faecal incontinence: Congenital=13 Iatrogenic=13 Obstetric=10 Neurogenic=9 Trauma=4 Idiopathic=2 Perineal colostomy=2	Implantation of Acticon ABS	*Inclusion* Not stated *Exclusion* Not stated	*Safety* Adverse events post-operatively and during follow-up *Effectiveness* Primary: Continence and quality of life Secondary: Functionality of device	Mean=26.5±14 months (range=7–55)

(Dodi et al 2000) University of Padova, Italy	IV Quality assessment: Fair	Pre-test/post-test case series	8 females with severe faecal incontinence Mean age=56 years (range=48–64) Aetiology of faecal incontinence: Idiopathic=6 Malformative=1 Traumatic=1	Implantation of Acticon ABS	*Inclusion* Not stated *Exclusion* Not stated	*Safety* Adverse events post-operatively and during follow-up *Effectiveness* Primary: Continence scores using AMS scale, functionality of device	Mean=10.5 months (range=4–23)
(La Torre et al 2004) Rome, Italy	IV Quality assessment: Poor	Pre-test/post-test case series	8 patients, 7/8 had severe faecal incontinence, 1/8 had undergone abdominoperineal resection 25 years earlier 2 males, 6 females Mean age=56.5 years (range=35–76) Aetiology of faecal incontinence: Rectal prolapse=1 Vertebral trauma=1 Iatrogenic=5	Implantation of Acticon ABS	*Inclusion* Not stated *Exclusion* Not stated	*Safety* Adverse events post-operatively and during follow-up *Effectiveness* Primary: CCCS, anorectal manometry and AMS QOL	Mean=26.3 months (range=3–40)
(Lehur et al 1998) Note: Some patients received AMS 800 urinary sphincter	IV Quality assessment: Fair	Pre-test/post-test case series	13 consecutive patients with severe faecal incontinence 4 males, 9 females Median age=40 years (range=22–60) Aetiology of faecal incontinence: Anal agenesia=4 Trauma=4 Neurogenic=5	Implantation of Acticon ABS (n=4) or AMS 800 urinary sphincter (n=9)	*Inclusion* Not stated *Exclusion* Not stated	*Safety* Adverse events post-operatively and during follow-up *Effectiveness* Primary: CCCS and functionality of device	Mean=30 months
(Lehur et al 2000) Nantes, France; Sagunto,	IV Quality assessment: Fair	Pre-test/post-test case series	24 patients with severe faecal incontinence 7 males, 17 females Median age=44 years (range=14–80)	Implantation of Acticon ABS	*Inclusion* Not stated *Exclusion* Not stated	*Safety* Adverse events post-operatively and during follow-up *Effectiveness*	Median=20 months (range=6–35)

Spain; Brussels, Belgium Note: Overlap of four patients with Lehur et al (1998)			Median duration of faecal incontinence =7.5 years (range=1–33) Aetiology of faecal incontinence: Anal trauma=6 Neurogenic=6 Anal trauma and neurogenic=3 Imperforate anus=3 Rectal prolapse=2			Primary: Continence using AMS faecal incontinence scores, functionality of device	
(Lehur et al 2002) Nantes, France Note: Some overlap of patients with Lehur et al (1998) and Lehur et al (2000)	IV Quality assessment: Fair	Pre-test/post-test case series	16 patients with anal incontinence 2 males, 14 females Mean age=43 years (range=19–64) Mean duration of faecal incontinence=5 years (range=1–33) Aetiology of faecal incontinence: Anal trauma=5 Pudendopathy=2 Anal trauma plus pudendopathy=2 Neurologic=2 Imperforate anus=3 Rectal prolapse=2	Implantation of Acticon ABS	*Inclusion* Not stated *Exclusion* Not stated	*Safety* Adverse events post-operatively and during follow-up *Effectiveness* Primary: Continence using AMS faecal incontinence scores, QOL Secondary: Functionality of device	Mean=25 months (range=7–49)
(Michot et al 2003)	IV Quality assessment: Fair	Pre-test/post-test case series	37 patients with severe faecal incontinence Two groups of patients: First 12 (implanted before October 1996): 5 males, 7 females Mean age= 53.6 years (range=43–63) Second 25 (implanted between October 1996	Implantation of Acticon ABS (28) and urinary sphincter (9)	*Inclusion* Not stated *Exclusion* Not stated	*Safety* Adverse events post-operatively and during follow-up *Effectiveness* Primary: Incontinence scores Secondary: Functionality of device	In first group of 12 patients, follow-up > 5 years In second group of 25 patients, mean follow-up=34.1 months (range=7–60)

			and April 2001): 10 males, 15 females Mean age=51.1 years (range=22–73) Mean duration of faecal incontinence in all patients=16 years (range=2–37) Aetiology of faecal incontinence: Obstetric trauma=7 Iatrogenic=10 Trauma=2 Hereditary malformation=2 Neurologic disorders=16				
(O'Brien & Skinner 2000) Melbourne, Australia	IV Quality assessment: Poor	Pre-test/post-test case series	13 patients with severe faecal incontinence 3 males, 10 females Median age=44 years (range=16–71) Mean duration of faecal incontinence =12.7 years Aetiology of faecal incontinence: Obstetric injury=8 Imperforate anus=2 Spina bifida=1 Anal canal surgery=2	Implantation of Acticon ABS	*Inclusion* Not stated *Exclusion* Not stated	*Safety* Adverse events post-operatively and during follow-up *Effectiveness* Primary: CCCS scores, AMS QOL and functionality of device	Not stated
(O'Brien et al 2004) Melbourne, Australia	II Quality assessment: Good	Randomised controlled trial	14 patients with severe anal incontinence *Acticon ABS group* 7 patients (1 male, 6 females) Mean age=66 years (range=46–75) Mean duration of faecal incontinence=7.6 years (range=3–20)	Implantation of Acticon ABS *Control group* Conservative therapy including physiotherapy for pelvic floor and sphincter muscles ± biofeedback, electrostimulation and defecation	*Inclusion* Severe faecal incontinence as defined by CCISS score ≥ 15, normal dexterity, ability to understand requirements of use of Acticon ABS *Exclusion* History of chronic perianal sepsis, taking immunosuppresants, history	*Safety* Adverse events post-operatively and during follow-up *Effectiveness* Primary: Continence and QOL Secondary: Functionality of device	6 months

			Control group 7 patients (7 females) Mean age=59 years (range=44–75) Mean duration of faecal incontinence=11.3 years (range=4–30)	retraining	of IBD; ongoing diarrhoea or high anaesthetic risk (ASA score >2)		
(Ortiz et al 2002) Spain	IV Quality assessment: Fair	Pre-test/post-test case series	22 patients with severe faecal incontinence 5 males, 17 females Mean age=47 years (range=17–72) Mean duration of faecal incontinence =18 years (range=2–39) Aetiology of faecal incontinence: Neuropathy=5 Anal atresia=3 Perineal trauma=3 Iatrogenic sphincter disruption=4 Obstetric injury=6 Steinert's dystrophy=1	Implantation of Acticon ABS	*Inclusion* Not stated *Exclusion* Not stated	*Safety* Adverse events post-operatively and during follow-up *Effectiveness* Primary: Continence Secondary: Functionality of device	Mean=28 months (range=6–48)
(Ortiz et al 2003) Pamplona, Spain Note: Expected overlap among patients with (Ortiz et al 2002)	III-2 Quality assessment: Fair	Non-randomised, experimental trial	16 patients with severe faecal incontinence Mean duration of faecal incontinence=17.6 years (range=2–38) *Acticon ABS* 3 males, 5 females Aetiology of faecal incontinence: Trauma=2 Surgery=1 Neuropathy=2 Atresia=2 Steinert's dystrophy=1	Implantation of Acticon ABS Or Dynamic graciloplasty	*Inclusion* Patients with severe faecal incontinence refractory to or not amenable to existing surgical techniques *Exclusion* Not stated	*Safety* Adverse events post-operatively and during follow-up *Effectiveness* Primary: Continence Secondary: Functionality of device	*Acticon ABS* Median=44 months (interquartile range=13) *Dynamic graciloplasty* Median=39 months (interquartile range=15)

			Dynamic graciloplasty 3 males, 5 females Aetiology of faecal incontinence: Obstetrics=1 Trauma=1 Surgery=2 Neuropathy=2 Atresia=2				
(Parker et al 2003) Note: 26 patients in Group II were previously reported in Wong et al (2002) (Results of Group I will not be reported as they do not meet inclusion criteria for this review)	IV Quality assessment: Good	Pre-test/post-test case series	47 patients with severe faecal incontinence Group I – 10 patients who underwent implantation of modified urinary sphincter between 1989 and 1992 Group II – 37 patients of which 35 underwent implantation after 1996 9 males, 26 females Mean age=47 years (range=18–72) Aetiology of faecal incontinence in Group II: Obstetric=11 Anorectal trauma=11 Congenital defect=7 Prolapse=4 Back surgery=2 Neurogenic=2	Implantation of Acticon ABS	*Inclusion* Faecal incontinence score ≥ 88 Age > 18 years Faecal incontinence for at least 6 months Failure of prior treatment or no available treatment Adequate dexterity and mental capacity to operate pump Adequate soft tissue surrounding anal canal Intact rectum or neoanal canal *Exclusion* Faecal incontinence score ≤ 88 Crohn's disease IBS as only cause of faecal incontinence Pelvic sepsis Pregnancy History of extensive pelvic radiation that would compromise anal canal Anal receptive intercourse	*Safety* Adverse events relating to implantation of Acticon ABS *Effectiveness* Incontinence scores (AMS), FIQOL	Group II: Mean=39 months (range=12–60)
(Savoye et al 2000)	IV Quality assessment: Poor	Pre-test/post-test case series	12 consecutive patients with severe faecal	Implantation of Acticon ABS	*Inclusion* Patients with severe faecal	*Safety* Adverse events relating to	Mean=16 months (range=4–28)

Rouen University Hospital, Rouen, France			incontinence Mean age=51 years (range=23–68) Aetiology of faecal incontinence: Neurological disorders=7 Iatrogenic trauma=2 Obstetric trauma=1 Multiple associated causes=2		incontinence after failure of conservative treatment *Exclusion* Not stated	implantation of Acticon ABS *Effectiveness* Primary: Continence	
(Savoye-Collet et al 2006) Rouen, France	N/A Quality assessment: N/A	Case report	61 year old female with severe faecal incontinence	Implantation of Acticon ABS 6 months previously	N/A	Safety data	N/A
(Vaizey et al 1998) United Kingdom	IV Quality assessment: Fair	Pre-test/post-test case series	6 females with severe faecal incontinence Median age=53 years (range=32–58) Median duration of faecal incontinence=20 years (range=4–40) Aetiology of faecal incontinence: Obstetric trauma and lateral sphincterotomy=2 Obstetric damage only=1 Idiopathic sphincter weakness=2 Imperforate anus=1	Implantation of Acticon ABS	*Inclusion* Not stated *Exclusion* Not stated	*Safety* Adverse events relating to implantation of Acticon ABS *Effectiveness* Continence, functionality of device, QOL 6 weeks post activation of device	Median=9 months (range=4–12)
(Wong et al 2002) New York, Minnesota, California, Louisiana, Florida, Texas, Pennsylvania	IV Quality assessment: Good	Pre-test/post-test case series	115 patients with severe faecal incontinence 29 males, 86 females Mean age=49 years (range=18–81) Aetiology of faecal incontinence: Obstetric trauma=34	Implantation of Acticon ABS	*Inclusion* Faecal incontinence score ≥ 88 Postpubescent Faecal incontinence for at least 6 months At least one prior nonsurgical treatment	*Safety* Adverse events relating to implantation of Acticon ABS *Effectiveness* Faecal incontinence scores, anal manometry, FIQOL, HSQ	12 months

, Missouri, Georgia, Massachusetts, Rhode Island USA; Ontario, Alberta, British Columbia Canada; Madrid, Spain; Nantes, France			Neurologic=23 Congenital abnormality=23 Anorectal trauma=21 Miscellaneous=14		No adverse comorbidities Adequate dexterity and mental capacity to operate device Life expectancy > 2 years *Exclusion* Faecal incontinence score < 88 Crohn's disease IBS as only cause of faecal incontinence Active pelvic sepsis Pregnancy History of extensive pelvic radiation that would compromise anal canal Scarred and fragile perineum Anal receptive intercourse		

ABS=artificial bowel sphincter; CCCS= Cleveland Clinic Continence Score; IBD=inflammatory bowel disease; ASA=American Society of Anesthesiologists; QOL=quality of life; SF-36=Medical Outcome Study Short form-36; AMS=American Medical Systems; AMS QOL= American Medical Systems quality of life scale; BDI=Beck Depression Inventory; SD=standard deviation; DGP=dynamic graciloplasty; FIQOL=American Society of Colon and Rectal Surgeons (ASCRS) Fecal incontinence quality of life scale; N/A=not applicable; IBS=irritable bowel syndrome; HSQ=health status questionnaire

Appendix E Excluded studies

Narrative review

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Appendix F Scales of incontinence

The continence score is determined by adding points from the table below, which takes into account the type and frequency of incontinence and the extent to which it alters the patient's life. A score of 0 indicates perfect continence and a score of 20 indicates complete incontinence (Jorge & Wexner 1993).

Cleveland Clinic continence grading scale

	Frequency				
	Never	**Rarely (<1/month)**	**Sometimes (<1/week, ≥ 1/month)**	**Usually (< 1/day, ≥ 1/week)**	**Always (≥ 1/day)**
Solid	0	1	2	3	4
Liquid	0	1	2	3	4
Gas	0	1	2	3	4
Wears pad	0	1	2	3	4
Lifestyle alteration	0	1	2	3	4

Source: Jorge & Wexner 1993

The Faecal Incontinence Scoring System (FISS) comprises a self-administered questionnaire of five questions. The first four questions relate to the frequency and type of incontinence (ie solid, liquid or gas). The fifth question relates to the impact incontinence has on lifestyle. Each response is assigned a numerical value which corresponds with severity and impact. The highest value response from questions one to four is added to the numerical value from question five and this determines the faecal incontinence score. For example, minor bowel soiling which in the last 4 weeks had been experienced weekly and had affected lifestyle sometimes would receive a score of 43, to which 2 would be added, giving a faecal incontinence score of 45.

Faecal Incontinence Scoring System (FISS) developed by Wong et al (2002)

Experience in last 4 weeks	**Never**	**Rarely (once in past 4 weeks)**	**Sometimes (> once in past 4 weeks, < once/week)**	**Weekly (≥ once/week, < once/day)**	**Daily (once/day)**	**Several times a day (> once/day)**
Accidental bowel leakage of gas	0	1	7	13	19	25
Minor bowel soiling or seepage	0	31	37	43	49	55
Significant accidental bowel leakage of liquid stool	0	61	73	85	97	109
Significant accidental bowel leakage of solid stool	0	67	79	91	103	115
How often accidental bowel leakage affected lifestyle	0	1	2	3	4	5

Glossary

Anal atresia	Congenital absence of an opening at the bottom end of the intestinal tract; also called imperforate anus
Anal fistula	An abnormal connection between two structures; in this case, one of these structures is the anus
Decubitus	Pressure sore or ulcer
End colostomy	The functioning end of the intestine is used to form the stoma by cuffing the intestine back on itself and suturing the end to the skin. The distal portion of bowel (now connected only to the rectum) may be removed, or sutured closed and left in the abdomen
Hirschsprung's disease	A congenital condition in which the colon does not have the normal network of nerves; there is little urge to defecate so there is accumulation of faeces, which can cause megacolon
Iatrogenic	Condition caused by the action, manner or treatment by a physician
Lithotomy position	The position of lying on the back with knees bent and elevated above the hips with the thighs apart
Imperforate anus	Congenital absence of an opening at the bottom end of the intestinal tract; also called anal atresia
Myasthenia gravis	A disorder of neuromuscular function characterised by muscular weakness and fatigue
Procidentia	Prolapse; rectal procidentia can be distinguished from haemorrhoids by the presence of mucosal folds
Puborectalis sling	A muscle originating at the posterior surface of the pubis which assists in maintaining the anorectal angle
Rectal capacity	The property of the rectum to act as a reservoir during rectal filling
Rectopexy	The surgical placement of sutures inside the rectum to return it to its proper position
Rigid sigmoidoscopy	Examination of the rectum using a thin, lighted tube called a proctoscope; also called proctoscopy

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