Placement of Artificial Bowel Sphincters in the Management of Faecal Incontinence

May 2003

MSAC application 1053

Assessment report

ISBN 0 642 82159 3

ISSN (Print) 1443-7120

ISSN (Online) 1443-7139

First printed September 2003.

Electronic copies of the report can be obtained from the Medical Service Advisory Committee's Internet site at:

http://www.msac.gov.au/

Hard copies of the report can be obtained from:

The Secretary
Medical Services Advisory Committee
Department of Health and Ageing
Mail Drop 107
GPO Box 9848
Canberra ACT 2601

Enquiries about the content of the report should be directed to the above address.

The Medical Services Advisory Committee is an independent committee which has been established to provide advice to the Commonwealth 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.

This report was prepared by the Medical Services Advisory Committee with the assistance of Ms Linda Mundy, Mrs Tracy Merlin and Professor Janet Hiller from the Health Technology Assessment Unit, Department of Public Health, University of Adelaide, and Professor Guy Madden, Department of Surgery, University of Adelaide. The report was endorsed by the Commonwealth Minister for Health and Ageing on August 11, 2003.

Publication approval number: *3156*

Contents

Tables

Figures

Executive summary

The procedure

The proposed intervention is the surgical implantation of an artificial bowel sphincter (ABS), which aims to control faecal incontinence by mimicking the natural action of the sphincter muscle. This device consists of three components: an inflatable cuff (the sphincter) which occludes the anal canal, a pressure-regulating balloon in the retroperitoneal space and a control pump placed in the scrotum or labia. The control pump regulates the movement of fluid from the balloon to the cuff and is operated manually by the patient and allows for the peristaltic passage of faeces.

Medical Services Advisory Committee – role and approach

The Medical Services Advisory Committee (MSAC) is a key element of a measure taken by the Commonwealth Government to strengthen the role of evidence in health financing decisions in Australia. The MSAC advises the Commonwealth 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 the available evidence is thus the basis of decision-making when funding is sought under Medicare. A team from the Health Technology Assessment Unit, Department of Public Health, University of Adelaide was engaged to conduct a systematic review of the literature on the placement of artificial bowel sphincters in the management of faecal incontinence. A supporting committee with expertise in this area then evaluated the evidence and provided advice to the MSAC.

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

Only case series and case reports (level IV evidence) on the implantation of the artificial bowel sphincter for the management of faecal incontinence were available for inclusion in this assessment. None of these studies included a control group. A direct comparison with dynamic graciloplasty could not be undertaken, as controlled studies were not available in which the Acticon™ Neosphincter was compared to dynamic graciloplasty. An indirect comparison with dynamic graciloplasty was not undertaken as the evidence for both procedures was low level and of poor quality.

Clinical need

The estimated prevalence of faecal incontinence in the general Australian population ranges from 0.9 to 14.9 per cent. This rate differs in various sub-populations; for example, women who have experienced pregnancy have reported rates ranging from 0 to 17.4 per cent, depending on parity, delivery mode and time post-partum. The elderly (≥65 years of age) are considered an at-risk group, with reported rates as high as 20 and

14.3 per cent in males and females respectively. Prevalence studies have not revealed the severity or degree of this faecal incontinence and hence it is difficult to estimate the number that would require implantation with the artificial bowel sphincter. In the year July 2001 to June 2002, the Medicare Benefit Schedule (MBS) processed seven claims for the one-step dynamic graciloplasty procedure, the most similar treatment alternative, which may indicate the level of clinical need for the procedure under review.

Safety

Good quality data were unavailable for the assessment of safety. Low-level evidence indicated a number of safety issues such as a high explantation rate affecting 30.5 per cent of patients. There was also a high rate of adverse events due to infection, device malfunction, ulceration and pain, which in many cases required additional surgical revision procedures (133 revision procedures in 272 patients).

Effectiveness

There were no studies available that assessed the effectiveness of the implantation of an artificial bowel sphincter to treat faecal incontinence in comparison to dynamic graciloplasty. All studies included in this assessment were flawed in their appraisal of outcomes in that patient results were not analysed on an intention-to-treat basis, thus misrepresenting the effectiveness of the procedure.

From the low-level evidence available, it would appear that for the majority of patients the procedure has uncertain benefits. It is clear that patient selection is critical to ensure the safe and effective implantation of the ABS. There is a select group of individuals in whom the procedure has a positive effect on their degree of continence and quality of life. Overall, 68.4 per cent of patients implanted with an ABS had a functioning device at the end of follow-up. These patients experienced an average 62 per cent improvement in their faecal continence levels. The remaining 31.6 per cent of patients had a non-functioning device or were explanted and did not have outcome data presented.

Methodological deficiencies that need to be addressed include the supply of all short- and long-term outcome data on an intention-to-treat basis, specifically quality of life and continence status, of all patients implanted with an ABS, including explanted patients.

Cost-effectiveness

An analysis of the cost-effectiveness of this procedure was not possible due to the lack of high quality evidence on clinical effectiveness and safety.

Recommendation

As insufficient evidence pertaining to the safety and effectiveness of the placement of artificial bowel sphincters in the management of faecal incontinence has emerged since this technology was previously considered by the MSAC, the MSAC recommends that public funding should not be supported for this procedure.

The Minister for Health and Ageing accepted this recommendation on August 11, 2003.

Introduction

The Medical Services Advisory Committee (MSAC) has reviewed the use of the Acticon™ Neosphincter, 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 artificial bowel sphincters in the management of faecal incontinence.

Background

Placement of artificial bowel sphincters in the management of faecal incontinence

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). Normal continence results from the interaction of several factors such as mental function, colonic transit, rectal distensibility, stool volume and consistency, anal sphincter function, anorectal reflexes and anorectal sensation (Madoff et al 1992). A disruption in one or more of these functions may result in faecal incontinence. There is no universal definition of faecal incontinence in current use by medical practitioners, leading to uncertainty in the diagnosis of patients and difficulties estimating the prevalence and impact of the condition in society.

The causes of faecal incontinence are diverse (Table 1), the most common cause being obstetric-related structural sphincter damage. Many other cases result from iatrogenic damage such as anal fistula caused during surgical procedures. 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). 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).

Faecal incontinence is a debilitating condition that can be socially and personally incapacitating. There are two types of faecal incontinence, passive and urgent. Passive faecal incontinence, where patients are not aware of 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. Patients experiencing urgent faecal incontinence are unable to postpone defaecation 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).

Table 1 Causes of faecal incontinence

Pelvic floor	Type of incontinence	Causative factor
Normal	Diarrhoeal states	Gastrointestinal diseases Laxative abuse
	Overflow	Impaction Encopresis Rectal neoplasms
	Neurological conditions	Multiple sclerosis Congenital anomalies Dementia, strokes, tabes dorsalis Neuropathy eg as a result of diabetes Neurological neoplasms Neurological injury
Abnormal	Congenital	Congenital anorectal malformation
	Trauma	Accidental injury, eg impalement, pelvic fracture Obstetrical injury Anorectal surgery
	Ageing	Degenerative changes of sphincter mechanism
	Pelvic floor degeneration (idiopathic neurogenic incontinence)	Vaginal delivery Chronic straining at stool Rectal prolapse Descending-perineum syndrome

Source: Madoff et al (1992)

The procedure

Scott and colleagues first used artificial sphincters in 1973 for the treatment of urinary incontinence (Scott et al 1973). Christiansen and Lorentzen adapted the American Medical Systems (AMS) urinary sphincter, AMS 800®, for the treatment of severe faecal incontinence in 1987 (Christiansen & Lorentzen 1987).

In 1996 American Medical Systems (AMS) released a modified version of the urinary sphincter specifically for use around the bowel, called the artificial bowel sphincter (ABS) or the Acticon™ Neosphincter. The ABS device consists of three components: an inflatable cuff (the sphincter), a pressure regulating balloon and a control pump. The inflatable cuff is inserted around the upper anal canal, occluding it, thus mimicking the natural function of the sphincter muscle. Tubing from the cuff is channeled along the perineum and connects to a control pump, which is made accessible to the patient by subcutaneous placement in either the scrotum or the labia. The control pump is connected by tubing to a pressure-regulating balloon, which has been implanted in the abdominal wall and is filled with radiopaque solution (40 ml). The control pump regulates the transfer of fluid from the balloon to the cuff and has a button that enables the patient to deactivate or activate the pump. When the cuff is inflated with the solution, continence is achieved. By compressing the control pump several times, the cuff is deflated, fluid is displaced from the cuff back to the pressure-regulating balloon

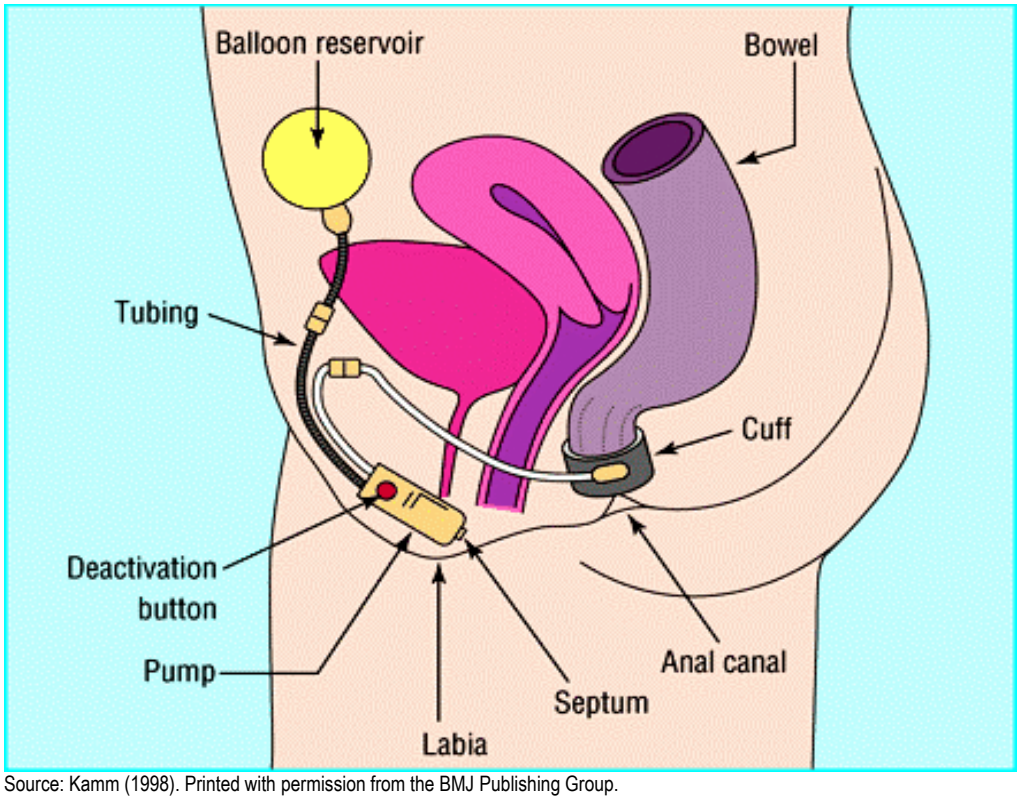
and defaecation can take place. Once defaecation is complete the cuff is slowly compressed again by the return of fluid from the pressure-regulating balloon and continence is again achieved. This process takes approximately 7-10 minutes (Figure 1) (Vaizey et al 1998a; Vaizey et al 1998b; Wong et al 1996). Further adaptations from the urinary sphincter include a larger pump, which enables rapid emptying of the larger volume of fluid from the cuff. The addition of a septum to the pump allows for the fine adjustment of the fluid volume by percutaneous injection or aspiration (Vaizey et al 1998a).

The device has a range of options:

- three different cuff widths: 2.0 cm (narrow), 2.9 cm (standard) and 3.4 cm (wide);
- cuff lengths ranging from 7 to 12 cm; and
- a pressure-regulating balloon available in seven different pressure ranges: 51-60 up to 111-120 cmH_2O (Vaizey et al 1998a; Vaizey et al 1998b).

The patient's skin is prepared with disinfectant 36-48 hours pre-operatively. During this time the bowel is prepared by the administration of an enema or whole-gut irrigation. Prophylactic antibiotics are administered at commencement of general anaesthesia and are continued for 1-7 days post-operatively (Altomare et al 2001; Lehur et al 1998; Lehur et al 2000). The duration of the procedure can range from 90 to 250 minutes (Altomare et al 2001). Patients are hospitalised for a mean period of eight days and may be fasted during post-operative care to prevent bowel movements. The implanted device remains inactivated to allow wound healing for up to two months (Dodi et al 2000; Lehur et al 1998).

Figure 1 Placement of the artificial bowel sphincter



Source: Kamm (1998). Printed with permission from the BMJ Publishing Group.

Intended purpose

Artificial bowel sphincters are indicated for post-pubescent patients with clinically documented severe faecal incontinence for whom non-surgical methods have either failed to provide adequate continence or are not an option. Faecal incontinence is defined in accordance with incontinence scoring systems such as that developed by the Cleveland Clinic (Table 2), where complete continence is indicated by a score of 0 and complete incontinence by a score of 20 (Jorge & Wexner 1993). Patients indicated for implantation with an ABS would usually score ≥ 18 using this system (Vaizey et al 1998a).

Table 2 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

20 points = complete incontinence, 0 points = complete continence
Source: Jorge and Wexner (1993)

Indications for the device are:

- hereditary malformations such as spina bifida or anal imperforation;
- neurological diseases such as diabetic neuropathy, myasthenia gravis and cauda equina neurinoma;
- destruction of the sphincter above its hemi-circumference due to obstetric trauma, surgical sequelae or trauma; and
- neuropathy in the absence of a sphincter defect (Michot et al 1997).

This device is contraindicated in patients:

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

The prosthesis is controlled by the operation of the pump and requires some manual dexterity and strength on behalf of patients. This may be a consideration for patient

selection. In addition, vaginal delivery of children may interfere with the functioning of the device (Rotholtz & Wexner 2001).

Clinical need / burden of disease

Morbidity associated with faecal incontinence is difficult to estimate, with reports of as few as 34.0 per cent of incontinence sufferers seeking help from a physician (Johanson & Lafferty 1996). Many patients are reluctant to seek medical assistance due to the associated social stigma and embarrassment. As a consequence, the condition remains largely unreported and undiagnosed (Lam et al 1999).

In total, 35 papers that examined the prevalence of faecal incontinence in different sections of the community were assessed for this review. There were no standard definitions of faecal incontinence between studies and outcome measures also varied greatly, making comparisons difficult.

Ten papers studied the prevalence of faecal incontinence in the general community (Table 3). Five of these studies were conducted in Australasia, two in the United States, two in the United Kingdom and one in Switzerland. All of these studies utilised cross-sectional surveys with randomly selected subjects. The response rates for these studies ranged from 48.0-95.4 per cent with an average of 69.9 ± 14.0 per cent. Nine of these studies were conducted via postal questionnaire. The remaining study was a questionnaire conducted by telephone. Recent data from two Australian studies, based on anonymous postal questionnaires sent randomly to voters registered on the electoral roll, suggest that the prevalence of faecal incontinence is much higher than previously estimated (11.2-15.0%) (Kalantar et al 2002; Lam et al 1999). Other population based studies estimate total prevalence rates of faecal incontinence, ranging from 0.9-16.5 per cent, with marked differences in rates between males and females (Bytzer et al 2001; Drossman et al 1993; Edwards & Jones 2001; Faltin et al 2001a; Lynch et al 2001; MacLennan et al 2000; Nelson et al 1995; Perry et al 2002).

Table 3 Prevalence of faecal incontinence in general population[a]

Prevalence of faecal incontinence (%)													
Study	**Country**	**Faecal incontinence**			**Incontinent to solid stool**			**Incontinent to liquid stool**			**Incontinent to flatus**		
		Tot	**M**	**F**	**Tot**	**M**	**F**	**Tot**	**M**	**F**	**Tot**	**M**	**F**
Bytzer et al (2001)	Australia	0.9											
Drossman et al (1993)	USA	7.8	7.9	7.7									
Edwards and Jones (2001)	UK	2.79	1.0	4.0									
Faltin et al (2001)	Switzerland	4.4											
Kalantar et al (2002)	Australia	11.2			2.0			9.0					
Lam et al (1999)	Australia	14.9	20.0	11.1									
Lynch et al (2001)	New Zealand	16.5	17.3	15.5									
MacLennan et al (2000)	Australia	2.9	2.3	3.5							8.9	6.8	5.6
Nelson et al (1995)	USA	2.3											
Perry et al (2002)	UK	1.4											

[a] Profiles including raw prevalence data are provided in Appendix C
Tot = total in population, M= male, F= female

The elderly are at greater risk of developing faecal incontinence due to age-related denervation of the external anal sphincter and pelvic floor muscles. One study from the United States, with a response rate of 65.9 per cent, assessed the prevalence of faecal incontinence in those aged 50 years or more in the general population (Table 4). Four studies from Australia, Japan, United States and the United Kingdom investigated the prevalence in the over 65 years age group in the general population (Table 5). All of these studies were cross-sectional surveys and all, except the in-home interview study by Nakanishi et al (1997), were postal questionnaires. The response rate for these studies was 73.2 ± 15.1 per cent. The 1999 Australian study by Lam and colleagues estimated faecal incontinence in the over 65 years age bracket at 20.0 and 14.3 per cent in males and females respectively, whereas other studies found lower rates (Lam et al 1999; Nakanishi et al 1997; Perry et al 2002; Roberts et al 1999; Talley et al 1992).

Table 4 Prevalence of faecal incontinence in general population ≥ 50 years of age[a]

Prevalence of faecal incontinence (%)				
Study	**Country**	**Tot**	**M**	**F**
Roberts et al (1999)	USA	13.1	11.0	15.0

[a] Profiles including raw prevalence data are provided in Appendix C
Tot = total in population, M= male, F= female

Table 5 Prevalence of faecal incontinence in general population ≥ 65 years of age[a]

Prevalence of faecal incontinence (%)				
Study	**Country**	**Tot**	**M**	**F**
Lam et al (1999)	Australia	n.a.[b]	20.0	14.3
Nakanishi et al (1997)	Japan	3.6		
Perry et al (2002)	UK	2.3		
Talley et al (1992)	USA	3.7		

Tot = total in population, M= male, F= female, n.a. = not available
[a] Profiles including raw prevalence data are provided in Appendix C
[b] Author did not provide population numbers for ≥65 years of age; therefore, total can not be calculated.

Four studies (a prospective cohort and three cross-sectional surveys) assessed the prevalence of faecal incontinence in nursing home populations (Table 6). Estimates of faecal incontinence commonly ranged from 45.6–63.0 per cent (Chassagne et al 1999; Johanson et al 1997; Nelson et al 1998). Conflicting results were reported by Peet and colleagues, who estimated prevalence of faecal incontinence in nursing homes in Leicestershire to be 3.1 per cent (Peet et al 1995). This disparity may be attributable to differing definitions of faecal incontinence or to methodological differences in data collection.

Table 6 Prevalence of faecal incontinence in nursing home residents[a]

Prevalence of faecal incontinence (%)										
Study	**Country**	**Faecal incontinence**			**Incontinent to solid stool**			**Incontinent to liquid stool**		
		Tot	**M**	**F**	**Tot**	**M**	**F**	**Tot**	**M**	**F**
Chassagne et al (1999)	France	49.0								
Johanson et al (1997)	USA	45.6	63.0	48.0		44.0	22.5		32.5	24.0
Nelson et al (1998)	USA	47.0	46.5	46.5						
Peet et al (1995)	UK	3.1								

Tot = total in population, M= male, F= female, [a] Profiles including raw prevalence data are provided in Appendix C

Prevalence rates of faecal incontinence amongst women of child-bearing age can be up to eight times higher than in men of the equivalent age, mainly due to obstetric complications (Jorge & Wexner 1993). Fifteen papers examined the prevalence of faecal incontinence in pregnant and post-partum women (Table 7). Eight of these studies were European based, three were from the United Kingdom, two were North American and two were conducted in the Middle East. Of these studies, nine were conducted on a consecutive series of women who answered a questionnaire, four recruited a prospective cohort of women and the remaining two were cross-sectional surveys. Depending on

parity and mode of delivery, faecal incontinence rates in these women ranged from 0–23.0 per cent (Abramowitz et al 2000; Chaliha et al 2001; Crawford et al 1993; Donnelly et al 1998; Eason et al 2002; Faltin et al 2001a; Faltin et al 2001b; Fornell et al 1996; Groutz et al 1999; Hojberg et al 2000; Macarthur et al 2001; Rizk et al 2001; Sultan et al 1993; Varma et al 1999; Zetterstrom et al 1999).

Table 7 Prevalence of faecal incontinence in pregnant and post-partum women[a]

Prevalence of faecal incontinence (%)					
Study	**Country**	**Faecal incontinence**	**Incontinent to solid stool**	**Incontinent to liquid stool**	**Incontinent to flatus**
Abramowitz et al (2000)	France	pre-delivery = 6.4 post-delivery = 13.7			
Chaliha et al (2001)	UK	pre-delivery = 9.3 post-delivery = 13.0			
Crawford et al (1993)	USA		with rupture = 3.0 without rupture = 0	with rupture = 3.0 without rupture = 3.0	with rupture = 17 without rupture = 3.0
Donnelly et al (1998)	Ireland	total = 3.8 caesarean = 0 vaginal = 1.4 instrument = 23.0			
Eason et al (2002)	Canada		total = 3.1 caesarean = 1.8 vaginal = 3.2		total = 25.5 caesarean = 22.8 vaginal = 25.9
Faltin et al (2001)	Switzerland	3 months pp[a] = 17.4 30 months pp = 14.3			
Faltin et al (2001)	Switzerland	8.1			
Fornell et al (1996)	Sweden		with rupture[b] = 0 without rupture[c] = 0	with rupture[b] = 16.0 without rupture[c] = 13.0	with rupture[b] = 24.0 without rupture[c]= 32.0
Groutz et al (1999)	Israel	7.0			
Højberg et al (2000)	Denmark	8.6	0.2	1.3	5.9
MacArthur et al (2001)	UK and New Zealand		0.3		1.2
Rizk et al (2002)	United Arab Emirates	11.3	5.5	5.8	14.4
Sultan et al (1993)	UK			primiparous = 1.3 multiparous = 8.3	primiparous = 3.8 multiparous = 8.3
Varma et al (1999)	UK	primiparous = 0 secundiparous = 0			
Zetterström et al (1999)	Sweden	pre-partum = 0.7 5 months pp[d] = 1.8 9 months pp = 1.1			pre-partum = 7.2 5 months pp[d]= 25.2 9 months pp = 25.5

[a] Profiles including raw prevalence data are provided in Appendix C

[b] with rupture = rupture of anal sphincter during vaginal delivery, [c] without rupture = anal sphincter was not ruptured during vaginal delivery, [d] pp = post-partum

Prevalence rates of faecal incontinence are also high in specific adult patient groups such as those suffering from multiple sclerosis or urinary incontinence (Bakke et al 1996; Chia et al 1995; Gordon et al 1999; Khullar et al 1998; Leroi et al 1999). Two studies, one a prospective cohort in Norway and the other a consecutive series of patients in the United Kingdom, assessed the prevalence of faecal incontinence in patients with multiple sclerosis (Table 8). Again, there was disparity of results with prevalence estimates of 3.4 and 15.6 per cent respectively.

Table 8 Prevalence of faecal incontinence in multiple sclerosis patients[a]

Prevalence of faecal incontinence (%)		
Study	**Country**	**Rate**
Bakke et al (1996)	Norway	3.4
Chia et al (1995)	UK	15.6

[a] Profiles including raw prevalence data are provided in Appendix C

Three studies conducted in Israel, the United Kingdom and France looked at the prevalence of faecal incontinence in women with existing urinary incontinence in a series of consecutively recruited women who answered a questionnaire (Table 9). Results from these studies indicated a prevalence of faecal incontinence ranging from 16.4 to 29.3 per cent.

Table 9 Prevalence of faecal incontinence in urinary incontinent women[a]

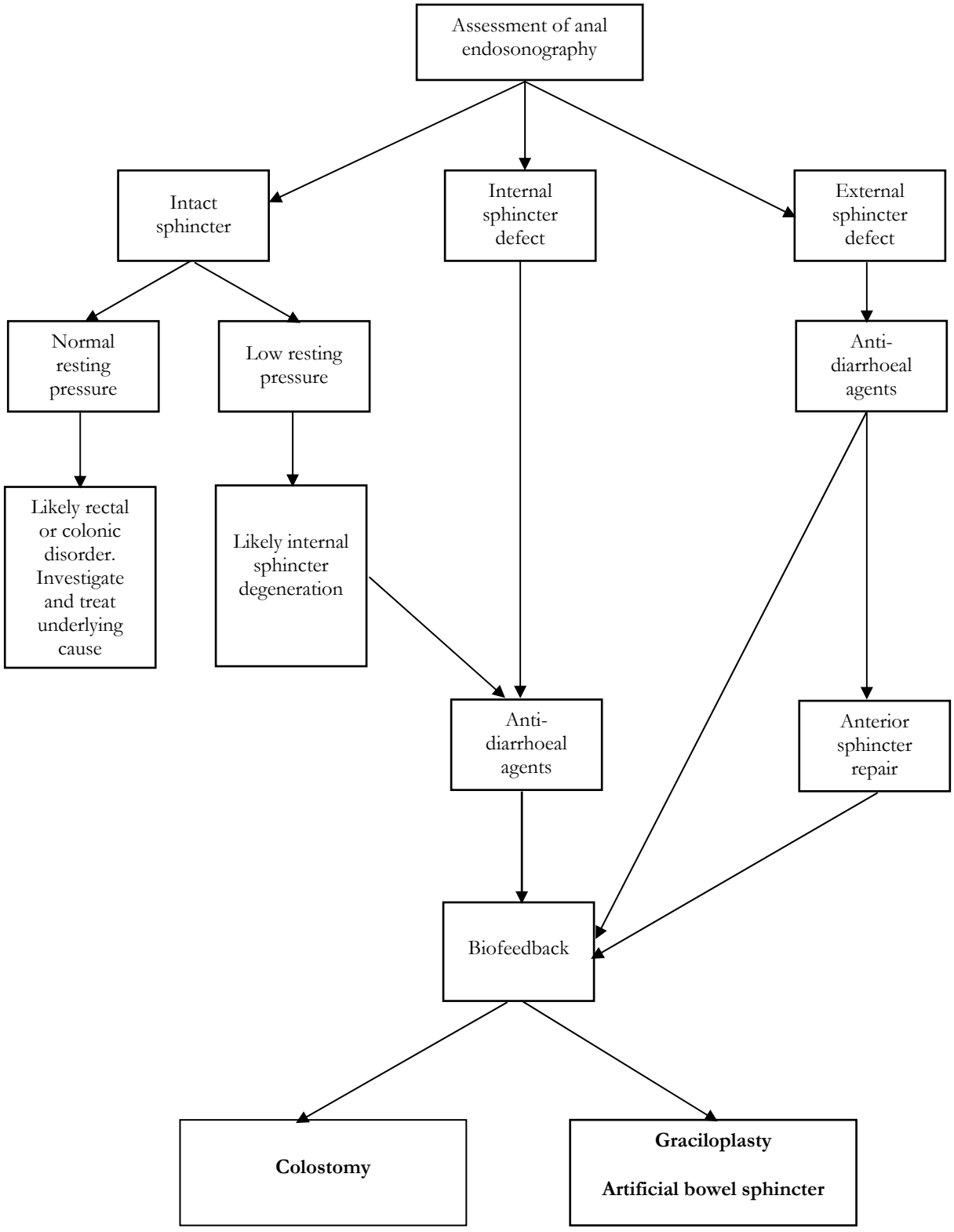
Prevalence of faecal incontinence (%)					
Study	**Country**	**Faecal incontinence**	**Incontinent to solid stool**	**Incontinent to liquid stool**	**Incontinent to flatus**
Gordon et al (1999)	Israel	29.3	8.8	6.4	14.1
Khullar et al (1998)	UK	16.4			
Leroi et al (1999)	France	28.0	1.0	9.5	18.3

[a] Profiles including raw prevalence data are provided in Appendix C

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



Adapted from Cheetham et al (2001)

A broad range of treatment options are available at initial diagnosis and assessment, depending on the severity of the faecal incontinence. These include medical therapy, biofeedback and surgery. Mild incontinence may improve with conservative treatment regimes such as a high fibre diet to increase stool bulk. Patients experiencing strong bowel contractions or leakage due to sphincter weakness can benefit from treatment with anti-diarrhoeal medication such as loperamide or codeine phosphate, which reduce motility of the large bowel, increase absorption and thus reduce stool weight.

Approximately two-thirds of patients benefit from biofeedback training which aims to condition patients to respond to stimuli and contract the external sphincter (Cheetham et al 2001). A small proportion of patients fail to respond to any of these treatment regimes and require surgical intervention. Surgical treatment options include sphincter repair, sacral nerve stimulation, encirclement procedures, muscle transposition (dynamic graciloplasty) and implantation with an ABS. Failure of all these treatment options may result in patients considering diversion surgery (colostomy) (Cheetham et al 2001; Jorge & Wexner 1993; Kamm 1998; Kamm 2002; Madoff et al 1992). The creation of a stoma during a colostomy may be considered the optimal choice for patients who do not wish to be subjected to the rigours of, or are not considered to be suitable candidates for, the above procedures. In addition, stoma creation may be the treatment of choice for those patients who are elderly, debilitated or institutionalised. Stoma diversion can be achieved either by laparotomy or laparoscopic means (Rotholtz & Wexner 2001).

Comparator

There is no device comparable to the artificial bowel sphincter (ie Acticon™ Neosphincter). The most appropriate comparator is dynamic graciloplasty, which involves the transposition of the gracilis muscle, a superficial adductor on the medial side of the thigh, to construct a neosphincter. The distal portion of the muscle encircles the anus whilst the proximal end remains anchored. The neurovascular bundle remains preserved. A low-frequency neurostimulator is implanted into the abdominal wall and electrodes inserted into the transposed muscle, which are then connected to an implanted battery. Chronic stimulation of the muscle via this neurostimulator converts it from Type II, fast-twitch, fatiguable muscle into slow-twitch, less fatiguable muscle, giving the muscle the properties required to function as a sphincter (Chapman 2001; Madoff et al 1999; Rotholtz & Wexner 2001; Vaizey et al 1998b). An external magnet allows patients to control stimulation. The muscle contracts when the neurotransmitter is activated and relaxes, allowing defaecation, when the neurotransmitter is deactivated (Baeten et al 1995). This procedure may be completed in either one or two operations. Stimulated dynamic graciloplasty was first performed by Baeten and colleagues in 1986 and is generally accepted to be the treatment option for severe faecal incontinence (Vaizey et al 1998b).

Marketing status of the device

The AMS artificial bowel sphincter prosthesis is registered on the Australian Register of Therapeutic Goods (TGA listing Aust L 12950).

Current reimbursement arrangement

Currently there is no listing on the Medicare Benefits Schedule (MBS) for the AMS artificial bowel sphincter prosthesis. The dynamic graciloplasty procedure is listed on the MBS (1 November 2002) under the following item numbers:

- Item 32203: Anal or perineal graciloplasty. Fee: $514.80
- Item 32206: Stimulator and electrodes, insertion of, following previous graciloplasty. Fee: $465.10
- Item 32209: Anal or perineal graciloplasty with insertion of stimulator and electrodes. Fee: $747.45

Approach to assessment

Review of literature

The medical literature was searched to identify relevant studies published or conducted between 1966 and August 2002. Table 10 describes the electronic databases that were used for this search.

Table 10 Electronic databases used for literature search

Electronic database	Time period
Medline (SilverPlatter)	1966 – August 2002
Embase (Embase.com)	1974 – August 2002
Current Contents (Ovid)	1993 – August 2002
Cochrane Library – including Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effectiveness, the Cochrane Controlled Trials Register, the Health Technology Assessment Database, the NHS Economic Evaluation Database	August 2002
Web of Science – Science Citation Index Expanded	1995 – August 2002
Proceedings First	1993 – August 2002

Two separate literature searches were conducted to encompass prevalence and outcomes. The search terms used are listed in Table 11. The full search strategies (based on the SilverPlatter platform) are provided in Appendix D.

Table 11 Search terms utilised for each area of inquiry

Area of inquiry	Search Terms
All searches	**MeSH** Fecal-Incontinence, Anus, Prostheses- and- Implants **Text words** Anal and incontinen*, f?ecal near incontinen*, artificial, Acticon, cuff, balloon, anal, bowel, sphincter, gracilo?plas*, Limits: not urin*, urethr*, achalasia, oesophag*, esophag*
Prevalence and prognosis/risk	**MeSH** Prevalence, Cross-sectional studies, Incidence, Cohort studies, Epidemiology, Natural history, Population characteristics, Risk **Text words** epidemiol*, prevalen*, inciden*, natural histor*, risk*, cohort*, population, registry or register

The following electronic internet databases were searched for relevant literature up until August 2002:

- Scirus – for Scientific Information Only (http://www.scirus.com);
- Trip database (http://www.tripdatabase.com);

- International Society of Technology Assessment in Health Care (http://www.istahc.org/en/welcome.html);
- International Network for Agencies for Health Technology Assessment (http://www.inahta.org/);
- National Library of Medicine Health Services / Technology Assessment Text (http://text.nlm.nih.gov/); and
- National Library of Medicine Locator Plus database (http://locatorplus.gov).

More recent listings of reports were located and searched at the websites of health technology assessment agencies up until August 2002 (see Appendix E).

Pearling

All included articles had their reference lists searched for additional relevant source material.

Inclusion criteria

The following inclusion criteria were applied to the identified citations:

- patients were post-pubescent with clinically determined severe faecal incontinence in whom conservative, non-surgical and surgical methods had failed to provide adequate continence;
- the proposed intervention was the implantation of the American Medical Systems ABS, the Acticon ™ Neosphincter or the AMS 800 for the management of faecal incontinence;
- the studies were conducted on humans; and
- publication language was restricted to English.

The study selection process went through six phases (see Figure 3).

Figure 3 Study selection process

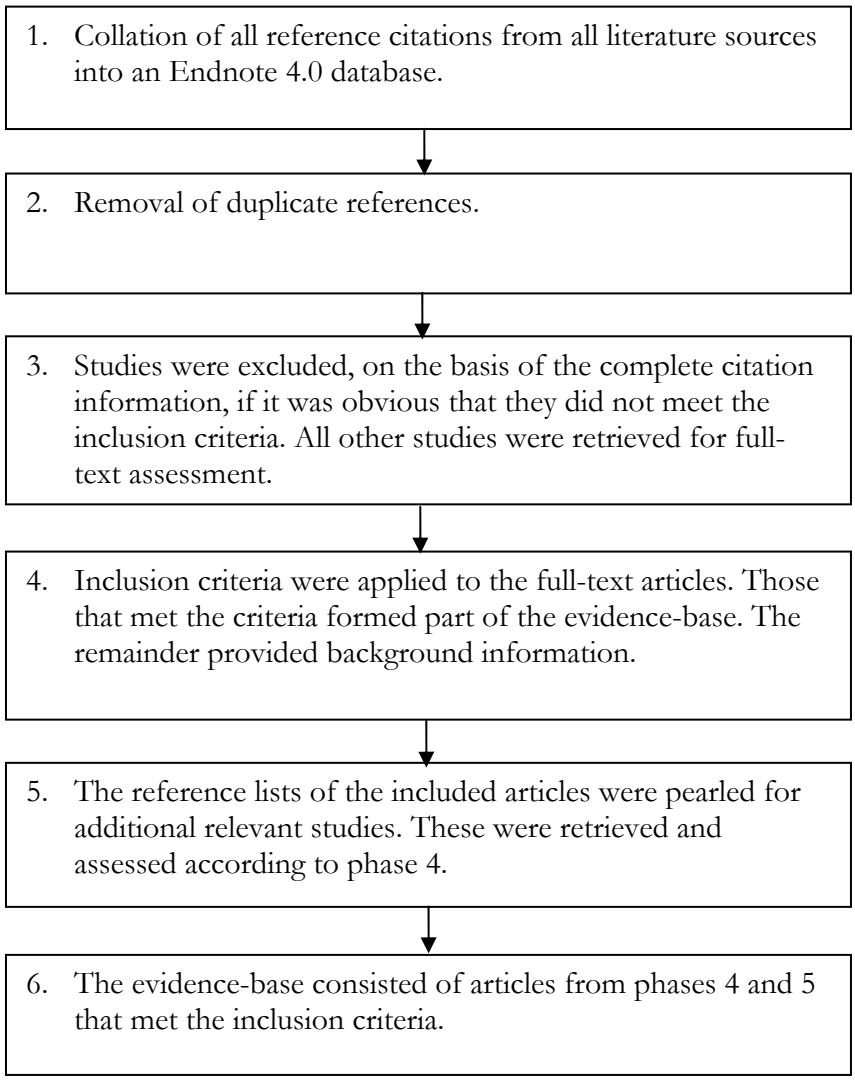


Table 12 provides a breakdown of the study selection process in terms of the number of citations retrieved and retained from each search.

Table 12 Number of citations initially retrieved and then retained at each phase

Search	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5	Phase 6
Prevalence	2780	2272	105	35	0	35
Safety and effectiveness	4658	3190	41[a]	12[a]	0	12
Total	7438	5462	146	47	0	47

[a] Total includes AMS's unpublished study (2002)

Twelve studies satisfied the inclusion criteria and were assessed, including the applicant's unpublished study.[1] Twenty-nine papers were excluded for the following reasons:

- nine papers were narrative reviews;
- seven papers were letters to the Editor;
- six studies used an intervention that was not AMS;
- one study was a preliminary report;
- one study was non-English; and
- five studies had data included in another study.

The excluded studies are presented in Appendix F.

Data extraction and analysis

Data were extracted from the included articles by a single researcher using tables developed *a priori* and outcome definitions provided in the original protocol.

Descriptive statistics were extracted or calculated for all safety and effectiveness outcomes in the individual studies, including numerator and denominator information, means and standard deviations.

Mean differences and 95 per cent confidence intervals (95%CI) were calculated for normally distributed continuous outcomes in individual studies using the related samples t-test.

All statistical calculations and testing were undertaken using the biostatistical computer package Stata version 7.0 (Stata Corporation 2001).

1. This study has since been published by Wong et al (2002). A recent study by Devesa et al (2002) published in October has not been included for analysis in this report. This study was a case series of 53 patients and outcomes of this study were not analysed on an intention-to-treat basis. The results of this study would not alter the outcome of this report.

Critical appraisal

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 2000).

These dimensions (Table 13) 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. The last two require expert clinical input as part of its determination.

Table 13 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.*
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.

*See Table 14

The three sub-domains (level, quality and statistical precision) are collectively a measure of the strength of the evidence. The designations of the levels of evidence are shown in Table 14.

Table 14 Designations of levels of evidence*

Level of evidence	Study design
I	Evidence obtained from a systematic review of all relevant randomised controlled trials
II	Evidence obtained from at least one properly-designed randomised controlled trial
III-1	Evidence obtained from well-designed pseudorandomised controlled trials (alternate allocation or some other method)
III-2	Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time series with a control group
III-3	Evidence obtained from comparative studies with historical control, two or more single arm studies, or interrupted time series without a parallel control group
IV	Evidence obtained from case series, either post-test or pre-test/post-test

*Modified from NHMRC, (1999).

The appraisal of controlled trials pertaining to the placement of artificial bowel sphincters in the treatment of faecal incontinence would have been undertaken using a checklist developed by Downs and Black (Downs & Black 1998). This checklist is suitable for trials and cohort studies and has been psychometrically assessed to have overall high internal consistency, good test–retest and inter-rater reliability, and high criterion validity. However, no controlled trials were available for assessment. Uncontrolled studies (in this case, pre-test/post-test case series) were assessed for their

quality using the checklist developed by Young and colleagues for case series (Appendix G) (Young et al 1999). The size of the effect and the clinical relevance of the evidence cannot be determined without the presence of a control group.

Expert advice

A supporting committee with expertise in colorectal surgery, geriatrics, general practice and stomal therapy/faecal incontinence was established to evaluate the evidence and provide advice to the MSAC from a clinical perspective. In selecting members for supporting committees, the MSAC's practice is to approach the appropriate medical colleges, specialist societies and associations, and consumer bodies for nominees. Membership of the supporting committee is provided at Appendix B.

Results of assessment

Twelve studies were identified for inclusion in this assessment of the safety and effectiveness of the ABS. Eleven of these studies were descriptive case series and therefore of low methodological quality (level IV evidence). Sample sizes in these studies ranged from 6 to 112 patients (American Medical Systems unpublished data 2002; Altomare et al 2001; Christiansen et al 1999; Dodi et al 2000; Lehur et al 1998, Lehur et al, 2000, Lehur et al, 2002; O'Brien & Skinner 2000; Ortiz et al 2002; Vaizey et al 1998a; Wong et al 1996). One paper was a case study and was assessed for safety data alone (Gelet et al 1997). Profiles of these studies are provided in Appendix C.

Duplication of results occurred in two studies by Lehur et al (2000, 2002). Four of the 24 patients from the 2000 study were first reported in the 1998 study and there was some duplication of patients in the 2002 study with the 1998 and 2000 studies, although numbers were not reported.

None of these studies compared the use of the ABS to dynamic graciloplasty; therefore, only data for the ABS are presented.

Is it safe?

Explantation of the ABS

All 11 case series recorded explantation rates (Table 15). These rates ranged from a low of 16.7 per cent in the study by Vaizey et al (1998a), with a mean follow-up period of 10 months post-implantation, to 50.0 per cent of patients in the study by Wong et al (1996), with a mean follow-up period of 58 months. It should be noted that the actual number of explantations in studies such as the AMS study (unpublished 2002), Lehur et al (2000) and Wong et al (1996) is higher due to explantation being followed by re-implantation and subsequent secondary explantation in some patients. The three studies conducted by Lehur and co-authors (1998, 2000, 2002) were of the highest quality due to their method of consecutive patient selection. These studies yielded explantation rates of 30.8, 29.2 and 31.3 per cent respectively. All of the other case series assessed had quality scores of 1.5/3 and were characterised by probable selection bias and lack of analysis of losses to follow-up.

Overall, a total of 272 patients were enrolled in all the studies and a total of 89 explants were performed in 83 (30.5%) patients, of which 72 were definitive. A definitive explant is described as being the permanent removal of the device. Reasons for explantation varied greatly from patient to patient. Infection accounted for nearly a quarter (23.6%) of all explants, with similar rates for erosion (21.4%) and combined infection and erosion (22.5%). Explants associated with device malfunction, such as cuff unbuttoning or rupture, accounted for 15.7 per cent. Other reasons for explantation included pain, incontinence and patient dissatisfaction.

Table 15 Explantation of device

Study	Level of evidence	Quality score	Length of follow-up	Population	Outcome: explants, pre-activation of device	Outcome: explants, post-activation of device	Total explantation rate
Lehur et al (2002)[a]	IV	2.5	Mean follow-up 25 months (range 7-49)	16 patients with severe FI[b] (2 male, 14 female)		4/16 definitive explantations *1/4 due to uncontrolled diarrhoea* *1/4 due to leakage* *1/4 due to cuff unbuttoning* *1/4 due to loss of radiopaque solution* 1/16[cd] explanted followed by re-implantation	5/16 (31.3%)
Lehur et al (2000)[e]	IV	2.5	Median follow-up 20 months (range 6-35)	24 patients (7 male, 17 female)	4/24 definitive explantation *2/4[d] due to erosion* *2/4 due to cuff rupture* *1/2[cf] patient underwent re-implantation followed by explantation due to infection* 3/24[cd] underwent temporary explantation due to cuff rupture, ulceration and pump malfunction. These patients were successfully re-implanted		8 explants in 7/24 (29.2%) patients
Lehur et al (1998)	IV	2.5	Median follow-up 30 months (range 5-76)	13 patients (4 male, 9 female) with severe FI	1/13[c] due to cuff rupture, followed by re-implantation 1/13[cd] due to anal stenosis, followed by re-implantation	1/13 at 5 years due to development of ulcerative colitis 1/13[c] due to patient dissatisfaction despite good functional results	4/13 (30.8%)

Altomare et al (2001)	IV	1.5	19 months (range 7-41)	28 women with severe FI > 1 year	4/28[c] due to infection and/or anal erosion	1/28[c] due to late infection	5/28 (17.9%)
American Medical Systems (unpublished study 2002)	IV	1.5	12 months follow-up	115 patients with severe FI (29 male, 86 female) Only 112 fitted with device		12/112[c] due to infection 12/112[cd] due to infection and erosion 11/112[d] due to erosion 2/112[g] due to incontinence and pain 1/112 due to ano-urethral communication	38 explants in 34/112 (30.4%) patients
Christiansen et al (1999)	IV	1.5	Mean ≥ 5 years (median 7, range 5-10)	17 patients with severe FI (6 male, 11 female)	2/17[c] due to infection	1/17[cd] due to late infection from cuff erosion 2/17 due to mechanical malfunction 1/17 due to chronic diarrhoea 1/17 due to obstructed defaecation	7/17 (41.2%)
Dodi et al (2000)	IV	1.5	Mean follow-up 10.5 months (range 4-23)	8 women with severe FI	2/8[cd] due to infection caused by cuff erosion		2/8 (25.0%)
O'Brien & Skinner (2000)	IV	1.5	No follow-up time given	13 patients with severe FI (3 male, 10 female)	1/13[c] due to infection	1/13[c] due to late infection 1/13[d] due to erosion, followed by infection	3/13 (23.1%)
Ortiz et al (2002)	IV	1.5	Mean follow-up 28 months (range 6-48)	22 patients with severe FI (5 male, 17 female)	2/22[cf] due to infection; one of these patients underwent re-implantation	2/22[g] due to chronic pain 1/22[c] due to unbuttoning of cuff; patient underwent re-implantation 4/22[d] due to erosion	9/22 (40.9%)

Vaizey et al (1998a)	IV	1.5	Mean follow-up 10 months (range 5-13)	6 females with severe FI		1/6[d] due to erosion	1/6[d] (16.7%)
Wong et al (1996)	IV	1.5	Mean follow-up 58 months (range 30-76)	12 patients (7 male, 5 female)		3/12 definitive explantations at the end of follow-up *1/3 due to patient dissatisfaction despite good functional results* *1/3 due to development of incontinence after 4 years* *1/3[cg] explanted after revision for pain, followed by an infection* 1/12[cf] explanted due to infection, re-implanted 1/12[c] explanted due to cuff leak, re-implanted 1/12[c] explanted after pump leak, re-implanted, followed by explantation after balloon leak, followed by re-implantation	7 explants in 6/12 (50.0%) patients

[a] Duplication of some patients from 1998 and 2000 studies, [b] FI = Faecal incontinence, [c] see Table 16, [d] see Table 18, [e] duplication of 4 patients from 1998 in this study, [f] see Table 17, [g] see Table 19

Surgical revision

All studies with the exception of Dodi et al (2000) reported adverse events that required surgical revision or procedures, including re-implantation of the ABS (Table 16). The three highest quality studies by Lehur et al (1998, 2000, 2002) reported surgical revision in 46.2, 37.5 and 12.5 per cent of patients respectively. The number of revisions ranged from a low of 12.5 per cent (Lehur et al 2002) to as high as 50 per cent of patients (Wong et al 1996; AMS 2002).

Overall, there were 133 surgical revision procedures performed in 103/272 patients (37.9%). As with explantation, the number of patients affected by surgical revision was not an accurate reflection of the number of procedures that took place because some patients experienced more than one revision. The highest quality study by Lehur et al (1998) reported eight revisions in 6/13 (46.2%) patients; the AMS study (2002) reported 81 surgical revisions for 56 (50%) patients; the study by Christiansen et al (1999) described six revisions performed on seven (85.7%) patients; and in the case study by Gelet et al (1997) two surgical revision procedures were required on one patient. Re-

implantation of the ABS device following erosion, infection or device malfunction (such as cuff rupture or balloon leak) accounted for 13.5 per cent of surgical revision procedures. The most common reason for surgical revision was due to infection (26.3%) or erosion (21.1%). Problems arising from the ABS device, such as malfunction, cuff rupture, balloon and pump leaks or migration of the device, accounted for 25.6 per cent of revisions if grouped as one category. Other reasons for surgical revision included pain and discomfort (9.0%), patient dissatisfaction (3.0%) and faecal impaction/constipation or continued incontinence (9.8%).

Table 16 Surgical revision, procedures and/or re-implantation

Study	Level of evidence	Quality score	Length of follow-up	Population	Outcome: pre-activation of device	Outcome: post-activation of device	Total number of surgical revisions
Lehur et al (2002)[a]	IV	2.5	Mean follow-up 25 months (range 7-49)	16 patients with severe FI[b] (2 male, 14 female)[g]		1/16 explanted cuff, followed by full explantation 1/16[cd] re-implanted following erosion	2 revisions in 2/16 (12.5%) patients
Lehur et al (2000)[e]	IV	2.5	Median follow-up 20 months (range 6-35)	24 patients (7 male, 17 female)	1/24 pump replacement 1/24 repositioning of cuff	3/24 closure of stoma (2 were pre-existing) 3/24[cd] re-implanted following erosion, cuff rupture and pump malfunction 1/24[cf] re-implanted followed by explanation due to infection	9 revisions in 9/24 (37.5%) patients
Lehur et al (1998)	IV	2.5	Median follow-up 30 months (range 5-76)	13 patients (4 male, 9 female) with severe FI	1/13[c] re-implanted with device after cuff rupture 1/13[cd] re-implanted with device after anal stenosis 2/13 elected to have a temporary stoma which was closed 2 months post implantation	1/13[c] found device uncomfortable and had control pump repositioned surgically 3 times 1/13[g] relocation of balloon after chronic pain	8 revisions in 6/13 (46.2%) patients

Altomare et al (2001)	IV	1.5	19 months (range 7-41)	28 women with severe FI > 1 year	1/28 haematoma requiring surgical drainage 2/28 dehiscence of perineal wound requiring surgery 1/28 dehiscence of perineal wound requiring direct repair 1/28 surgical replacement of pressure balloon	1/28 cuff broken resulting in surgical replacement of cuff 1/28[d] cuff erosion resulting in surgical replacement of cuff	7 revisions in 7/28 (25.0%) patients
American Medical Systems (unpublished study 2002)	IV	1.5	12 months follow-up	115 patients with severe FI (29 male, 86 female) Only 112 fitted with device			81 revisions in 56/112 (50%) patients who experienced 395 device-related adverse events Number of device related revisions, expressed as percentage of patients, included infection (25%), erosion (21.4%), malfunction (9.8%), incontinence (8.9%), pain (5.4%) and patient dissatisfaction (3.6%), re-implantations (3.6%)
Christiansen et al (1999)	IV	1.5	Mean ≥ 5 years (median 7, range 5-10)	17 patients with severe FI (6 male, 11 female)		3 cuff replacement procedures after rupture 2 balloon replacement procedures after rupture 1 revision of tubing after infection 1 patient needed percutaneous refilling of fluid in balloon via device septum	6 revisions in 5/17 (29.4%) patients

O'Brien & Skinner (2000)	IV	1.5	No follow-up time given	13 patients with severe FI (3 male, 10 female)		2/13[h] became impacted, required dis-impaction under anaesthesia 1/13[g] device repositioning after pain 1/13 pump repositioning after adhesion to scrotum	4 revisions in 4/13 (30.8%) patients
Ortiz et al (2002)	IV	1.5	Mean follow-up 28 months (range 6-48)	22 patients with severe FI (5 male, 17 female)	2/22[cf] re-implantation following infection	1/22 required cuff refilling 1/22 pump migration, required surgical repositioning 1/22[c] cuff unbuttoning, required explantation followed by re-implantation 1/22[d] debridement and suture of wound after erosion	6 revisions in 6/22 (27.3%) patients
Vaizey et al (1998a)	IV	1.5	Mean follow-up 10 months (range 5-13)	6 females with severe FI	1/6 (16.7%) required dis-impaction under anaesthesia		1 revision in 1/6 (16.7%) patients

Wong et al (1996)	IV	1.5	Mean follow-up 58 months (range 30-76)	12 patients (7 male, 5 female)		1/12[cfg] device relocation following chronic pain, followed by infection and explantation 1/12[cf] re-implanted after infection 1/12[c] re-implanted after cuff leak 1/12[c] re-implanted due to pump leak, followed by explantation and re-implantation due to balloon leak 2/12[cf] had stoma created after explantation due to infection	7 revisions in 6/12 (50%) patients
Gelet et al (1997)	n.a.	n.a.	24 months	Case report of female patient with dual urinary and FI		Revision procedure due to mechanical failure Revision procedure for replacement of pressure balloon	2 revisions in 1 (100%) patient

[a] Duplication of some patients from 1998 and 2000 studies, [b] faecal incontinence, [c] see Table 15, [d] see Table 18, [e] duplication of 4 patients from 1998 in this study, [f] see Table 17, [g] see Table 19, [h] see Table 20

Infection

The risk of infection in patients undergoing this procedure is genuine, and may be increased in comparison to other surgical procedures, due in part to the implantation of a foreign object in the anorectal region (Christiansen 2000). All studies with the exception of Lehur et al (2002) and Gelet et al (1997) reported post-operative infection (Table 17). Infection of the perineal or abdominal surgical site occurred in most early infections (ie prior to the activation of the ABS). Thirteen early infections resulted in 11 explantations, despite the routine administration of post-operative antibiotics. The two high quality studies carried out by Lehur et al (1998, 2000) reported infection in 7.7 and 4.2 per cent of patients respectively. The eight lower quality studies reported rates of infection that ranged from 9.1 per cent to 33.3 per cent reported by Ortiz et al (2002) and Vaizey et al (1998a) respectively.

During the post-activation period, infection occurred in 45/272 patients (16.5%). Fifteen (33.3%) of these were the result of erosion, and explantation was the outcome in 31 (68.9%). Overall, there were a total of 63 infection events in 58/272 (21.3%) patients, resulting in 42 explants.

Table 17 Post-operative infection

Study	Level of evidence	Quality score	Length of follow-up	Population	Outcome: pre-activation of device	Outcome: post-activation of device	Total number of infection events
Lehur et al (2000)[a]	IV	2.5	Median follow-up 20 months (range 6-35)	24 patients (7 male, 17 female)		1/24[bc] infection of second implanted device resulting in explantation	1/24[bc] (4.2%)
Lehur et al (1998)	IV	2.5	Median follow-up 30 months (range 5-76)	13 patients (4 male, 9 female) with severe FI[d]	1/13		1/13 (7.7%)
Altomare et al (2001)	IV	1.5	19 months (range 7-41)	28 women with severe FI > 1 year	3/28[b] early infection of perineal and abdominal wounds followed by explantation 1/28[b] early infection of perineal wound alone followed by explantation	1/28[be] late infection caused by cuff erosion followed by explantation	5/28 (17.9%)
American Medical Systems (unpublished study 2002)	IV	1.5	12 months follow-up	115 patients with severe FI (29 male, 86 female) Only 112 fitted with device			41 infections in 36/112 (32.1%) patients[bce] 12/112 (10.7%) explanted due to infection alone[b] 12/112 (10.7%) explanted due to infection and erosion[b]
Christiansen et al (1999)	IV	1.5	Mean ≥ 5 years (median 7, range 5-10)	17 patients with severe FI (6 male, 11 female)	2/17[b] infection followed by explantation	1/17[be] late infection caused by cuff erosion followed by explantation	3/17 (17.6%)
Dodi et al (2000)	IV	1.5	Mean follow-up 10.5 months (range 4-23)	8 women with severe FI	2/8[be] infection caused by cuff erosion followed by explantation		2/8[be] (25.0%)

O'Brien & Skinner (2000)	IV	1.5	No follow-up time given	13 patients with severe FI (3 male, 10 female)	1/13[b] leading to explantation	1/13[b] leading to explantation 1/13[be] infection from erosion, leading to explantation	3/13 (23.1%)
Ortiz et al (2002)	IV	1.5	Mean follow-up 28 months (range 6-48)	22 patients with severe FI (5 male, 17 female)	2/22[bc] perineal infection leading to explantation; one of these patients underwent re-implantation		2/22[bc] (9.1%)
Vaizey et al (1998a)	IV	1.5	Mean follow-up 10 months (range 5-13)	6 female patients with severe FI	1/6 poor wound healing	1/6 infection over balloon site	2/6 (33.3%)
Wong et al (1996)	IV	1.5	Mean follow-up 58 months (range 30-76)	12 patients (7 male, 5 female)		1/12[b] infection leading to explantation followed by re-implantation 1/12 infection 1/12[bc] infection after relocation of device followed by explantation	3/12 (25.0%)

[a] Duplication of 4 patients from 1998 in this study, [b] see Table 15, [c] see Table 16, [d] faecal incontinence, [e] see Table 18

Erosion or ulceration

Careful placement of the ABS cuff around the anal canal to prevent slippage against the perianal skin is essential to prevent tissue erosion in this region (Christiansen 2000). Erosion or ulceration of the perineal or groin region occurred in 10 of the 12 studies with the exception of the Gelet et al (1997) and Wong et al (1996) studies (Table 18). The three high quality studies by Lehur et al (1998, 2000, 2002) reported erosion in 7.7, 12.5 and 6.3 per cent of patients respectively. Erosion rates ranged from the low reported by Christiansen et al (1999) of 5.9 per cent to the highest value of 25.0 per cent of patients, reported by Dodi et al (2000). In total, 42/272 (15.4%) patients experienced 46 events of erosion or ulceration caused by the device. A total of 31/46 (67.4%) erosion events led to explantation, 18 (58.1%) of these from erosion or ulceration alone and the remaining 13 (41.9%) due to erosion followed by infection.

Table 18 Ulceration or cuff erosion

Study	Level of evidence	Quality score	Length of follow-up	Population	Outcome: pre-activation of device	Outcome: post-activation of device	Total number of erosion events
Lehur et al (2002)[a]	IV	2.5	Mean follow-up 25 months (range 7-49)	16 patients with severe FI[b] (2 male, 14 female)		1/16[cd] explanted due to erosion, followed by re-implantation	1/16[cd] (6.3%)
Lehur et al (2000)[e]	IV	2.5	Median follow-up 20 months (range 6-35)	24 patients (7 male, 17 female)	1/24 erosion in groin 1/24[cd] ulceration, explanted device, re-implanted	1/24 erosion of perineum	3/24 (12.5%)
Lehur et al (1998)	IV	2.5	Median follow-up 30 months (range 5-76)	13 patients (4 male, 9 female) with severe FI	1/13[cd] ulceration		1/13[cd] (7.7%)
Altomare et al (2001)	IV	1.5	19 months (range 7-41)	28 women with severe FI > 1 year		3/28[df] cuff erosion. 1 patient required surgical revision	3/28[df] (10.7%)
American Medical Systems (unpublished study 2002)	IV	1.5	12 months follow-up	115 patients with severe FI (29 male, 86 female) Only 112 fitted with device			28 erosion events in 24/112 (21.4%) patients[cdf] 11/112 (9.8%) explanted due to erosion alone[b] 12/112 (10.7%) explanted due to erosion and infection[b]
Christiansen et al (1999)	IV	1.5	Mean ≥ 5 years (median 7, range 5-10)	17 patients with severe FI (6 male, 11 female)		1/17[f] cuff erosion	1/17[f](5.9%)
Dodi et al (2000)	IV	1.5	Mean follow-up 10.5 months (range 4-23)	8 women with severe FI	2/8[cf]		2/8[cf] (25.0%)
O'Brien & Skinner (2000)	IV	1.5	No follow-up time given	13 patients with severe FI (3 male, 10 female)		1/13[cf] erosion, followed by infection and explantation	1/13[cf] (7.7%)

Ortiz et al (2002)	IV	1.5	Mean follow-up 28 months (range 6-48)	22 patients with severe FI (5 male, 17 female)	5/22[cd] erosion with exteriorisation of cuff or tubes. 4[b] of these 5 underwent explantation		5/22[cd] (22.7%)
Vaizey et al (1998a)	IV	1.5	Mean follow-up 10 months (range 5-13)	6 females with severe FI		1/6[c] ulceration, followed by explantation	1/6[c] (16.7%)

[a] Duplication of some patients from 1998 and 2000 studies, [b] faecal incontinence, [c] see Table 15, [d] see Table 16, [e] duplication of 4 patients from 1998 in this study, [f] see Table 17

Chronic pain

Chronic pain was reported in seven of the 12 studies (Table 19). The better quality study by Lehur et al (1998) reported one patient out of 13 (7.7%) who experienced pain after implantation. The rate of chronic pain ranged from 3.6 per cent reported by Altomare et al (2001) to 33.0 per cent recorded by the AMS study (2002). The AMS study reported 44 events of pain in 37/112 (33.0%) patients but only eight of these required surgical revision. Forty-six patients (16.9%) experienced chronic pain, the majority of events occurring in the post-activation period, and 14 (5.1%) of these patients required surgical revision such as repositioning of the device.

Table 19 Chronic pain

Study	Level of evidence	Quality score	Length of follow-up	Population	Outcome: pre-activation of device	Outcome: post-activation of device	Total number of chronic pain events
Lehur et al (1998)	IV	2.5	Median follow-up 30 months (range 5-76)	13 patients (4 male, 9 female) with severe FI [a]		1/13[b] relocation of balloon after chronic pain	1/13[b] (7.7%)
Altomare et al (2001)	IV	1.5	19 months (range 7-41)	28 women with severe FI > 1 year		1/28 resulting in removal of cuff	1/28 (3.6%)
American Medical Systems (unpublished study 2002)	IV	1.5	12 months follow-up	115 patients with severe FI (29 male, 86 female) Only 112 fitted with device		2/112[c] resulting in device explants 6/112[b] resulting in device revisions	44 events in 37/112 (33.0%) patients 8/112[c] (7.1%) required surgical revision

O'Brien & Skinner (2000)	IV	1.5	No follow-up time given	13 patients with severe FI (3 male, 10 female)	2/13[b] had excessive discomfort; one of these patients had the device surgically repositioned		2/13[b] (15.4%)
Ortiz et al (2002)	IV	1.5	Mean follow-up 28 months (range 6-48)	22 patients with severe FI (5 male, 17 female)		3/22[c] 1 treated with analgesics, 2 explanted	3/22[c] (13.6%)
Vaizey et al (1998a)	IV	1.5	Mean follow-up 10 months (range 5-13)	6 female patients with severe FI		1/6 pain at cuff site	1/6 (16.7%)
Wong et al (1996)	IV	1.5	Mean follow-up 58 months (range 30-76)	12 patients (7 male, 5 female)		1/12[bc] painful location of device, relocated surgically then ultimately explanted	1/12[bc] (8.3%)

[a] Faecal incontinence, [b] see Table 16, [c] see Table 15

Faecal impaction or obstruction

Of the 12 studies included for assessment, six reported that patients implanted with an ABS had post-operative faecal impaction (Table 20). The better quality study conducted by Lehur et al (1998) reported 6/13 (46.2%) patients experienced obstructed defaecation that required regular enemas. Other studies reported rates ranging from a low of 5.9 per cent (Christiansen et al 1999) to 83.3 per cent (Vaizey et al 1998a). There were 53 events of obstructed defaecation or impaction in the 189 patients enrolled in these studies. Of these 53 events, 14/53 (26.4%) required regular enemas and 12/53 (22.6%) required medication or laxatives. The duration of these treatment regimes was not stated. Nine of the 53 (17.0%) events were more serious and required surgical intervention.

Table 20 Post-operative faecal impaction

Study	Level of evidence	Quality score	Length of follow-up	Population	Outcome	Total number of impaction events
Lehur et al (1998)	IV	2.5	Median follow-up 30 months (range 5-76)	13 patients (4 male, 9 female) with severe FI[a]	6/13 obstructed defaecation, needed regular enemas	6/13 (46.2%)

Altomare et al (2001)	IV	1.5	19 months (range 7-41)	28 women with severe FI > 1 year	12/28 obstructed defaecation *7/12 required daily enemas* *3/12 required manual evacuation* *2/12[b] cuff was deactivated*	12/28 (42.9%)
American Medical Systems (unpublished study 2002)	IV	1.5	12 months follow-up	115 patients with severe FI (29 male, 86 female) only 112 fitted with device	21/112 patients had 27 episodes of faecal impaction *3[c] of which required surgical intervention* *7 events required medication* *2 events required no treatment* *17 events required other intervention*	27 episodes in 21/112 (18.8%)
Christiansen et al (1999)	IV	1.5	Mean ≥ 5 years (median 7, range 5-10)	17 patients with severe FI (6 male, 11 female)	1/17[d] obstructed defaecation, needed regular enemas	1/17[d] (5.9%)
O'Brien & Skinner (2000)	IV	1.5	No follow-up time given	13 patients with severe FI (3 male, 10 female)	2/13[c] impacted, requiring disimpaction under anaesthesia	2/13[c] (15.4%)
Vaizey et al (1998a)	IV	1.5	Mean follow-up 10 months (range 5-13)	6 female patients with severe FI	5/6 using laxatives intermittently; one patient required disimpaction under anaesthesia	5/6 (83.3%)

[a] Faecal incontinence, [b] see Table 24, [c] see Table 16, [d] see Table 15

Other adverse events

Table 21 outlines adverse events associated with the implantation of the ABS other than those described in the above tables. The better quality study conducted by Lehur et al (2000) reported 41.7 per cent of patients experienced other adverse events. The AMS study (2002) reported 314 device related adverse events, excluding the 81 episodes that required device revision. Of these, 61/314 (19.4%) required surgical intervention. It is not clear how many patients were affected by adverse events in this study, as AMS reported that patients may have had more than one type of adverse event or may have experienced more than one event of the same type. Excluding the AMS study, 26/160

(16.3%) patients experienced other adverse events. Of these 26 patients, 14 (53.8%) experienced dehiscence of the perineal wound, two of which required a surgical revision procedure and one a direct repair. Other adverse events included the development of a rectocele, urinary tract infection, phlebitis, and perineal and abdominal haematoma.

Table 21 Other adverse events

Study	Level of evidence	Quality score	Length of follow-up	Population	Outcome: pre-activation of device	Total number of other adverse events
Lehur et al (2000)[a]	IV	2.5	Median follow-up 20 months (range 6-35)	24 patients (7 male, 17 female)[a]	2/24 dehiscence of perineal wound 2/24 developed a rectocele 1/24 developed leg phlebitis 5/24 developed urinary tract infection	10/24 (41.7%)
Altomare et al (2001)	IV	1.5	19 months (range 7-41	28 women with severe FI[b] > 1 year	9/28 dehiscence of perineal wound *2/9[c] required surgery* *1/9 required direct repair*	9/28 (32.1%)
American Medical Systems (unpublished study 2002)	IV	1.5	12 months follow-up	115 patients with severe FI (29 male, 86 female) Only 112 fitted with device		314 device-related adverse events not previously discussed [d]
Ortiz et al (2002)	IV	1.5	Mean follow-up 28 months (range 6-48)	22 patients with severe FI (5 male, 17 female)	4/22 perineal and abdominal haematoma 3/22 perineal wound dehiscence	7/22 (31.8%)

[a] Duplication of 4 patients from 1998 in this study, [b] faecal incontinence, [c] see Table 16, [d] Patients may have had more than one type of adverse event and may have more than one event of the same type.

All the studies assessed revealed numerous safety concerns such as the high rate of explantation and surgical revision. Currently there is no evidence indicating the benefits or harms associated with particular aspects of patient selection and management. It is clear, however, that patient selection is critical to ensure the safe implantation of the ABS. Patients should be suffering severe faecal incontinence and have exhausted all other avenues of conservative medical treatment, such as biofeedback, medical therapy and less rigorous surgery. Expert advice suggests that in future this procedure could become accepted clinical practice for the treatment of faecal incontinence; however, additional evidence would need to be provided before this could occur.

Is it effective?

Faecal incontinence scores

Comparison of continence outcomes across studies was difficult due to the use of three different continence measurement systems: the Williams, the AMS and the Cleveland Continence scales (Appendix H) (American Medical Systems unpublished data 2002; Christiansen et al 1999; Jorge & Wexner 1993).

Ten studies presented data on faecal incontinence scores pre- and post-implantation (Tables 22-24). The study by Altomare et al (2001) assessed faecal incontinence status using both the AMS and Cleveland measurement scales. The study by Wong et al (1996) measured continence but data were not provided.

Five studies utilised the AMS scale, which measures continence on a scale of 0 to 120, where 120 represents complete incontinence and 0 complete continence (Table 22). Two of the better quality studies by Lehur et al (2000, 2002) utilised this scale to assess levels of incontinence. The five studies provided pre-implantation faecal incontinence scores on all patients implanted with the ABS but only provided post-implantation scores on patients with a successful, functional outcome. Pre-implantation scores ranged from 70 to 120 points, while post-implantation scores ranged from 0 to 120.

Statistical analyses by the authors were not conducted on an intention-to-treat basis. As a result, all studies recorded significant differences in mean faecal incontinence scores from pre- to post-implantation for those patients with a functional ABS, indicating patients had a marked improvement in their continence status. A reduction of ≥ 24 points (20%) is regarded to be of clinical significance (American Medical Systems unpublished data 2002). Only one study, by Dodi et al (2000), provided raw data for individual patients; therefore, comparison between pre- and post-implantation could be made on the same patient group, yielding a mean difference of 76 points [95%CI 37.35, 114.65], a statistically and clinically significant improvement in continence. The other four studies provided only the p values from their analyses. The two studies by Lehur et al (2000, 2002) and Dodi et al (2000) reported significant differences in the means of pre- and post-implantation scores but there was great variability in the effect on patients, as shown by large standard deviations. The remaining two studies reported means and ranges, and also demonstrated large variability.

Overall, of the 175 patients who had pre-implantation scores measured using the AMS scale, 131 (74.9%) had post-implantation scores at six months follow-up. This number decreased further with post-implantation scores reported for 114 (65.0%) patients at the end of the follow-up period. These patients had an average improvement of 78.6 (± 14.2) points out of 120 or an average 65.5 per cent improvement in their continence at six months post-implantation.

Table 22 Faecal incontinence assessed using AMS scale

Study	Level of evidence	Quality score	Length of follow-up	Mean value pre-operatively	Mean value post-operatively	Statistical results
Lehur et al (2002)[a]	IV	2.5	Mean follow-up 25 months (range 7-49)	(n=14) mean 105 ± 14	*6 months* (n=14) 24 ± 25 *12 months* (n=10) 32 ± 34 *24 months* (n=5) 32 ± 28 *>24 months* (n= 6) 23 ± 22	p < 0.05[b] p < 0.05[b] p < 0.05[b] p < 0.05[b]
Lehur et al (2000)[c]	IV	2.5	Median follow-up 20 months (range 6-35)	(n=24) mean 106 ± 13	*6 months* (n=23) 19 ± 32 *12 months* (n=17) 25 ± 29 *end of follow-up* (n=20) 25 ± 25	p < 0.0001[b] p < 0.0001[b] p < 0.0001[b]
Altomare et al (2001)	IV	1.5	19 months (range 7-41)	(n=28) median 98.5 range 75-120	(n=21) median 5.5 range 0-49	p < 0.001[d]
American Medical Systems (unpublished study 2002)	IV	1.5	12 months follow-up	(n=101)[f] mean 106 range 71-120	*6 months* (n=67) mean 50 range 0-108 *12 months* (n=61) mean 49 range 0-120	t = -13.73[e] p <0.0001 t = -14.28[e] p <0.0001
Dodi et al (2000)	IV	1.5	Mean follow-up 10.5 months (range 4-23)	(n=8) mean 95.0 ± 12.0 range 70-108	(n=6) mean 19.4 ± 19.3 range 0-61	Mean difference = 76 ± 36.8 95%CI [37.35,114.65] p = 0.0039

[a] Duplication of some patients from 1998 and 2000 studies, [b] authors' statistical analysis using t-test for paired comparisons and Wilcoxon rank sum test, p values only, no statistics given, [c] duplication of 4 patients from 1998 in this study, [d] authors' statistical analysis using Wilcoxon rank sum test, p values only, no statistics given, [e] Authors' statistical analysis using Dunnett t-test

Five studies utilised the Cleveland faecal incontinence measurement scale, including one of the better quality studies by Lehur et al (1998) (Table 23). The Cleveland scale measures continence on a scale of 0 to 20, where 0 represents complete continence and 20 complete incontinence. The five studies provided pre-implantation faecal incontinence scores on all patients implanted with the ABS but only provided analysis on post-implantation scores of patients with a successful, functional outcome. Pre-implantation scores ranged from 11 to 20 points, while post-implantation scores ranged from 0 to 14.

The functional outcome cited in the paper by Vaizey et al (1998a) was not calculated on an intention-to-treat basis but raw data were available to make this possible. This study yielded a significant difference between pre- and post-implantation scores ($p< 0.001$) with a mean difference of 15 points [95%CI 9.44, 20.55], a clinically significant improvement in continence of 75 per cent when analysed on an intention-to-treat basis. The better quality study by Lehur et al (1998) provided raw data for the 11 patients who had a successful outcome; therefore, comparison between pre- and post-implantation could be made on the same patient group. This yielded a mean difference of 12.5 points [95%CI 9.95, 15.13], a 62.5 per cent improvement in continence, which is statistically and clinically significant. The other three studies provided only the p values from their own analyses.

Of the 82 patients who had pre-implantation scores measured using the Cleveland scale, 63 (76.8%) had post-implantation scores. These patients had an average improvement of 14.1 (± 1.8) points out of 20 or a 70.5 per cent improvement in their continence at end of follow-up. A 20 per cent improvement is considered clinically significant.

Table 23 Faecal incontinence assessed using Cleveland Clinic scale

Study	Level of evidence	Quality score	Length of follow-up	Mean value pre-operatively	Mean value post-operatively	Statistical results
Lehur et al (1998)	IV	2.5	Median follow-up 30 months (range 5-76)	(n=13) mean 17 ± 1.8 range 14-20	(n=11) mean 4.5 ± 3.4 range 0-10	Mean difference = 12.5 ± 3.9 95%CI [9.95, 15.13] p < 0.0001
Altomare et al (2001)	IV	1.5	19 months (range 7-41)	(n=28) median 14.9 range 11-20	(n=21) median 2.6 range 0-6	p < 0.001[a]
O'Brien & Skinner (2000)	IV	1.5	No follow-up time given	(n=13) 18.7 ± 1.6	(n=10) 2.1 ± 2.6	p < 0.001[b]
Ortiz et al (2002)	IV	1.5	Mean follow-up 28 months (range 6-48)	(n=22) mean 18 range 14-20	(n=15) mean 4 range 0-14	p < 0.001[a]
Vaizey et al (1998a)	IV	1.5	Mean follow-up 10 months (range 5-13)	(n=6) mean 19.5 ± 0.8 range 18-20	(n=6) mean 4.5 ± 4.9 range 0-13	Mean difference = 15 ± 5.3 95%CI [9.44, 20.55] p = 0.001

[a] Authors' statistical analysis using Wilcoxon rank sum test, p values only, no statistics given, [b] authors' statistical analysis, no method stated

Only the study by Christiansen et al (1999) utilised the Williams scale, which measures continence on a scale of one to five, where one represents complete continence and five, complete incontinence (Table 24). This study provided pre-implantation faecal incontinence scores on all patients implanted with the ABS but only presented post-implantation data on 8/17 (47%) patients who had a successful, functional outcome. Pre-implantation scores for all patients were five, while post-implantation scores ranged from one to four. Raw data were provided for these successful patients; therefore, comparison between pre- and post-implantation could be made on the same patients, yielding a mean difference of 2.5 points [95%CI 1.73, 3.27], or a 50 per cent improvement in their continence at end of follow-up.

Table 24 Faecal incontinence assessed using Williams scale

Study	Level of evidence	Quality score	Length of follow-up	Mean value pre-operatively	Mean value post-operatively	Statistical results
Christiansen et al (1999)	IV	1.5	Mean ≥ 5 years (median 7, range 5-10)	(n=17) mean 5 ± 0	(n= 8) mean 2.5 ± 0.9	Mean difference = 2.5 ± 0.9 95%CI [1.73, 3.27] p= 0.0001

Of the total 257 patients with pre-implantation faecal incontinence data, only 180 (70%) had follow-up data during the first six months of follow-up. This rate decreased further in the two studies with longer follow-up times (Lehur et al 2000, 2002), such that a total of 169/257 (65.76%) patients had follow-up data presented.

All studies recorded statistically significant reductions in mean faecal incontinence scores from pre- to post-implantation for those patients with a functional ABS. Patients were not, however, analysed on an intention-to-treat basis; thus, the results only reflect the effect on responders and are not generalisable to all patients implanted with an ABS. Overall continence scores also do not reflect the number of patients who experienced changes or improvements in the type of incontinence such as incontinence to solid stool, liquid stool or flatus. Further, the lack of a control group in these studies makes it difficult to determine whether the improvement in continence status is the sole result of the procedure.

Quality of life

Five studies reported data on quality of life (QOL) measurements using four different methods of assessment (Tables 25-28), once again making comparison between studies difficult. Altomare et al (2001) and O'Brien & Skinner (2000) utilised the AMS QOL questionnaire, while Lehur et al (2002) used the faecal incontinence score developed by Rockwood (Rockwood et al 2000) and Vaizey et al (1998a) employed the Short Form-36 (SF-36) questionnaire (Ware et al 1993). The AMS study measured QOL using the AMS QOL scale but results were reported in a narrative fashion with no data presented. Data were presented, however, from the Health Status Questionnaire (HSQ 2.0) (American Medical Systems unpublished data 2002).

The Rockwood faecal incontinence QOL scale is composed of 29 items in four scales and has been shown to be reliable and valid (Rockwood et al 2000). The better quality study conducted by Lehur et al (2002) (Table 25) utilised a modified version of the Rockwood QOL scale, using 27 items and four domains. Each response to an item is assigned an optimal value of four with the worst scenario attracting a score of one. Points are added then divided by the maximum number of points possible. Scores can range from zero, being the worst case, to a maximum of one. Lehur et al (2002) provided pre- and post-implantation QOL data for only 10/16 (62.5%) patients, who all had a successful, functioning ABS at end of follow-up. The mean pre-implantation score was 0.44, with post-implantation scores of 0.86, 0.94, 0.83 and 0.84 at 6, 12, 24 and >24 months follow-up respectively. Post-implantation scores showed significant improvement in QOL when compared to pre-implantation scores ($p<0.05$).

Table 25 Quality of life assessed using a modified Rockwood QOL scale

Study	Level of evidence	Quality score	Population	Length of follow-up	Mean value pre-operatively	Mean value post-operatively	Statistical results
Lehur et al (2002)	IV	2.5	16 patients with severe FI[a] (2 male, 14 female)	Mean follow-up 25 months (range 7-49)	10/16 0.44 ± 0.14	10/16 *6 months* 0.86 ± 0.18 *12 months* 0.94 ± 0.06 *24 months* 0.83 ±0.16 *>24 months* 0.84 ± 0.15	 p <0.05[b] p <0.05[b] p <0.05[b] p <0.05[b]

[a] Faecal incontinence, [b] authors' statistical analysis using paired t-test, p values only, no statistics given

The AMS faecal incontinence QOL scale is a 39 item, self-administered questionnaire that is yet to be validated. QOL scores are expressed as percentages with 100 per cent representing the worst possible scenario. Table 26 gives the results of two studies that used the AMS scale to assess QOL.

Altomare et al (2001) reported median pre-implantation scores of 65 per cent, which fell to 8 per cent post-implantation. Although the authors do not clearly state which patients completed the QOL assessment, data were only presented pre- and post-implantation for 14/28 (50%) possible patients who underwent the procedure, despite 21/28 (75%) patients having a functional device at the end of follow-up. Altomare et al (2001) found a significant difference between the pre- and post-implantation QOL scores ($p<0.001$). The study by O'Brien & Skinner (2000) provided pre-implantation QOL scores for all 13 patients implanted with the ABS but post-implantation QOL data for only 10/13 (76.9%) patients, who all had a successful, functioning ABS at end of follow-up. The mean pre- and post-implantation scores were 77 and 12 per cent respectively at the end of follow-up, but there was great variability between patients, as shown by the large standard deviations. Post-implantation scores showed statistically and clinically significant improvements in QOL when compared to pre-implantation scores ($p<0.0001$).

Table 26 Quality of life assessed using AMS QOL questionnaire

Study	Level of evidence	Quality score	Population	Length of follow-up	Pre-operative value	Post-operative value	Statistical results
Altomare et al (2001)	IV	1.5	28 women with severe FI[a] > 1 year	19 months (range 7-41)	Median QOL 14/28[b] patients = 65%	Median QOL 14/28[b] patients = 8%	p <0.001[c]
O'Brien & Skinner (2000)	IV	1.5	13 patients with severe FI (3 male, 10 female)	No follow-up time given	QOL[d] (n=13) Mean 77 ± 16%	QOL[d] (n=10) Mean 12 ± 19%	p < 0.0001[d]

[a] Faecal incontinence, [b] 14/21 patients with functioning device were continent. Paper does not state if these 14 patients were the 14 that completed the QOL questionnaire, [c] authors' statistical analysis using Wilcoxon rank sum test, p values only, no statistics given, [d] authors' statistical analysis, no method stated, p values only, no statistics given

The HSQ 2.0 is a self-administered questionnaire with eight domains including social and physical functioning, health perception and mental health. Each domain is assessed on a scale of 0 to 100, with 100 representing ideal functioning (American Medical Systems unpublished data 2002).

The mean pre-implantation score was 457/800 and the mean post-implantation score was 555/800, over the eight domains. Post-implantation HSQ 2.0 scores showed significant improvement when compared to pre-implantation scores, with a mean difference of 97.94 over the eight domains ($p<0.0001$) (Table 27).

Table 27 Quality of life assessed using HSQ 2.0

Study	Level of evidence	Quality score	Population	Length of follow-up	Mean value pre-operatively	Mean value post-operatively	Statistical results
American Medical Systems (unpublished study 2002)	IV	1.5	115 patients with severe FI[a] (29 male, 86 female) Only 112 fitted with device	12 months follow-up	(n=48) 457/800	(n=48) 555/800	Mean difference = 97.94 SE = 19.53 t = 5.02 p<0.0001[b]

[a] Faecal incontinence, [b] authors' statistical analysis using paired t-test

Vaizey et al (1998a) employed the Short Form-36 (SF-36) questionnaire to assess QOL (Table 28). QOL is assessed across eight categories and scores range from 0 (poor) to 100 (excellent) (Ware et al 1993). Pre- and post-implantation data were only presented on the 5/6 (83.3%) patients who had a successful, functioning ABS at end of follow-up. Statistical analysis was not possible on this study as data were reported as mean scores and a range across each of the eight categories. No global score was given, and the sample size was too small to give any meaningful result.

Table 28 Quality of life assessed using SF36

Study	Level of evidence	Quality score	Population	Length of follow-up	Mean value pre-operatively	Mean value post-operatively
Vaizey et al (1998a)	IV	1.5	6 female patients with severe FI[a]	Mean follow-up 10 months (range 5-13)	(n=5) mean (range) emotional 0 (0-100) 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)	(n=5) mean (range) emotional 33 (0-100) 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)

[a] Faecal incontinence

Overall, only 90/175 (51.0%) patients who underwent implantation in these five studies had a pre-implantation QOL/HSQ 2.0 assessment completed. Of these 90 patients, 87 (96.7%) completed a post-implantation QOL/HSQ 2.0 questionnaire.

All studies recorded statistically significant differences in mean QOL/HSQ 2.0 scores from pre- to post-implantation for those patients with a functional ABS, with high mean differences indicating patients had a marked improvement in their quality of life. Patients were not, however, analysed on an intention-to-treat basis, as the QOL of explanted patients was not assessed. The analysis is flawed and likely to be unrepresentative of the QOL of all patients who received an ABS. The lack of a control group in these studies makes it difficult to determine whether the improvement in quality of life status is the sole result of the procedure.

Functioning device in patients at the end of follow-up period

At the end of follow-up, all of the 11 case series reported that between 53.3 and 84.6 per cent of patients had a functioning ABS device implanted (Table 29). The three better quality studies by Lehur et al (1998, 2000, 2002) reported 75 to 85 per cent of patients had a functioning device at the end of follow-up (approximately two years). The study by Christiansen et al (1999) had the longest follow-up period, with a mean of five years

(range 5-10) and reported the lowest rate of functioning device at 53.3 per cent, which may be an indication of the life span of the ABS device. Two patients died in this study from causes unrelated to the implantation of the ABS device and were removed from total patient numbers. Overall, there were 184/269 (68.4%) patients enrolled in all studies with a functioning device at the end of follow-up.

Table 29 Functioning device

Study	Level of evidence	Quality score	Population	Length of follow-up	Outcome
Lehur et al (2002)[a]	IV	2.5	16 patients with severe FI[b] (2 male, 14 female)	Mean follow-up 25 months (range 7-49)	12/16 (75%) functioning device
Lehur et al (2000)[c]	IV	2.5	24 patients (7 male, 17 female)	Median follow-up 20 months (range 6-35)	20/24 (83.3%) functioning device
Lehur et al (1998)	IV	2.5	13 patients (4 male, 9 female) with severe FI	Median follow-up 30 months (range 5-76)	11/13 (84.6%) functioning device
Altomare et al (2001)	IV	1.5	28 women with severe FI > 1 year	19 months (range 7-41)	21/28 (75%) functioning device
American Medical Systems (unpublished study 2002)	IV	1.5	115 patients with severe FI (29 male, 86 female) Only 112 fitted with device	12 months follow-up	67/112 (59.8%) functioning device
Christiansen et al (1999)	IV	1.5	17 patients with severe FI (6 male, 11 female)	Mean ≥ 5 years (median 7, range 5-10)	8/15 (53.3%) functioning device
Dodi et al (2000)	IV	1.5	8 women with severe FI	Mean follow-up 10.5 months (range 4-23)	6/8 (75%) functioning device
O'Brien & Skinner(2000)	IV	1.5	13 patients with severe FI (3 male, 10 female)	No follow-up time given	10/13 (76.9%) functioning device
Ortiz et al (2002)	IV	1.5	22 patients with severe FI (5 male, 17 female)	Mean follow-up 28 months (range 6-48)	15/22 (68.2%) functioning device

Vaizey et al (1998a)	IV	1.5	6 female patients with severe FI	Mean follow-up 10 months (range 5-13)	5/6 (83.3%) functioning device
Wong et al (1996)	IV	1.5	12 patients (7 male, 5 female)	Mean follow-up 58 months (range 30-76)	9/12 (75%) functioning device

[a] Duplication of some patients from 1998 and 2000 studies, [b] faecal incontinence, [c] duplication of 4 patients from 1998 in this study

Resting and squeeze anal manometry

Sphincter function and tone may be assessed by anorectal manometry. Resting anal pressure is a function of the internal sphincter whilst squeeze anal pressure reflects external sphincter function (Cheetham et al 2001). Nine of the eleven case series presented data on resting anal manometry measurements (Table 30) and two studies presented data on squeeze pressure (Table 31), pre- and post-implantation. The analogous physiological state, whilst implanted with the ABS, of resting anal pressure are measurements taken with the ABS cuff closed. An increase in anal resting pressure from pre- to post-implantation may indicate improved sphincter function; however, a strong correlation between resting pressures and continence status has not yet been established. Approximate normal anorectal resting pressures range from 40 to 80 mmHg (American Medical Systems unpublished data 2002).

The three good quality studies by Lehur (1998, 2000, 2002) reported post-implantation anal manometry pressures with both the cuff open and closed. Two of these studies (1998 and 2000) reported slightly elevated but statistically insignificant, post-implantation resting pressures with the cuff open. This small increase ensures that the pressure remains low enough to avoid tissue erosion (Lehur et al 1998). Interestingly, the 2002 study by Lehur and colleagues recorded a mean decrease of 7 mmHg when compared to resting anal pressures pre-implantation, which may reflect biological variation or measurement error. All three studies reported a significant difference when comparing the pre-implantation resting pressures to post-implantation pressures with the cuff closed ($p<0.0001$).

The remaining six studies by Altomare et al (2001), AMS (unpublished data 2002), Dodi et al (2000), Ortiz et al (2002), Vaizey et al (1998a) and Wong et al (1996) reported pre-implantation resting anal manometry readings compared to post-implantation anal manometry readings with the cuff closed or device activated. All of these studies found an increase in anal pressure post-implantation when compared to the pre-implantation resting pressures and, with the exception of the studies by Dodi et al (2000) and Wong et al (1996), the difference between the two measurements were statistically significant (Table 30). The study conducted by Dodi et al (2000) found no significant difference between the two measurements despite a large increase in post-implantation pressures, which may be due to the large standard deviation in the pre-implantation measurements. Similarly, the study by Wong et al (1996) found an increase in anal pressure post-implantation, the significance of which could not be determined due to lack of data.

Table 30 Anal manometry: Resting anal pressure

Study	Level of evidence	Quality score	Population	Length of follow-up	Pre-operative value	Post-operative value	Statistical analysis
Lehur et al (2002)[a]	IV	2.5	16 patients with severe FI[b] (2 male, 14 female)	Mean follow-up 25 months (range 7-49)	(n=16) mean 42 ± 24 mmHg	(n=12) mean 35 ± 27 mmHg (cuff open) mean 98 ± 23 mmHg (cuff closed)	NSD[c] p <0.0001[c]
Lehur et al (2000)[d]	IV	2.5	24 patients (7 male, 17 female)	Median follow-up 20 months (range 6-35)	(n=24) median 28 mmHg	(n=20) median 30 mmHg (cuff open) median 60 mmHg (cuff closed)	NSD[c] p< 0.0001[c]
Lehur et al (1998)	IV	2.5	13 patients (4 male, 9 female) with severe FI	Median follow-up 30 months (range 5-76)	(n=13) mean 41 ± 10 cmH_2O	(n=11) mean 48 ± 10 cmH_2O (cuff open) mean 72 ± 7 mmHg (cuff closed)	NSD[c] p <0.0001[c]
Altomare et al (2001)	IV	1.5	28 women with severe FI > 1 year	19 months (range 7-41)	(n=28) median 27 mmHg range 5-71 mmHg	(n=21) median 32 mmHg range 11-59 mmHg (cuff open) (n=21) median 67mmHg range 14-145 mmHg (cuff closed)	NSD[e] p <0.001[e]

American Medical Systems (unpublished study 2002)	IV	1.5	115 patients with severe FI (29 male, 86 female) Only 112 fitted with device	12 months follow-up	(n=106) mean 26 ± 15 mmHg (range 0-70)	(n=73) *At time of activation* of device mean 47 ± 17 mmHg (range 8-78) (n=61) *6 months* mean 46 ± 16 mmHg (range 12-80) (n=53) *12 months* mean 45 ± 16 mmHg (range 14-77)	p< 0.0001[f]
Dodi et al (2000)	IV	1.5	8 women with severe FI	Mean follow-up 10.5 months (range 4-23)	(n=8) mean 44.3 ± 21.3 mmHg	(n=6) mean 45.2 mmHg (cuff open) 72.5 mmHg (cuff closed)	NSD[cg] NSD[cg]
Ortiz et al (2002)	IV	1.5	22 patients with severe FI (5 male, 17 female)	Mean follow-up 28 months (range 6-48)	(n=22) mean 35 mmHg range 8-87	(n=15) mean 54 mmHg range 34-70 (cuff closed)	p< 0.01[e]
Vaizey et al (1998a)	IV	1.5	6 female patients with severe FI	Mean follow-up 10 months (range 5-13)	(n=6) mean 54.2 ± 22.5 cmH_2O	(n=5) mean 111 ± 8.9 cmH_2O (cuff closed)	mean difference = 53 ± 17.2 95%CI [31.7, 74.3] p = 0.0023
Wong et al (1996)	IV	1.5	12 patients (7 male, 5 female)	Mean follow-up 58 months (range 30-76)	(n=10) mean 16 mmHg	(n=9) mean 68 mmHg (cuff closed)	NE[h]

[a] Duplication of some patients from 1998 and 2000 studies, [b] faecal incontinence, [c] NSD = no significant difference at p>0.05, authors' statistical analysis using t-test and Wilcoxon's test, p values only, no statistics given, [d] duplication of 4 patients from 1998 in this study, [e] authors' statistical analysis using Wilcoxon's rank sum test, p values only, no statistics given, [f] authors' statistical analysis using paired t-test, p values only, no statistics given, [g] authors' statistical analysis using Students t-test, [h] NE = not estimable

The two studies by Altomare et al (2001) and Dodi et al (2000) compared pre-implantation squeeze anal pressures to post-implantation anal pressures with the ABS cuff closed and both authors found no differences between the two measurements (Table 31).

Table 31 Anal manometry: Squeeze pressure

Study	Level of evidence	Quality score	Population	Length of follow-up	Mean value pre-operatively	Mean value post-operatively	Mean difference
Altomare et al (2001)	IV	1.5	28 women with severe FI[a] > 1 year	19 months (range 7-41)	(n=28) median 42 mmHg range 11-110 mmHg	(n=21) median 67 mmHg range 14 - 145 mmHg (cuff closed)	NSD[b] p= 0.061
Dodi et al (2000)	IV	1.5	8 women with severe FI	Mean follow-up 10.5 months (range 4-23)	(n=8) mean 63.5± 28.3 mmHg range 20-92	(n=6) mean 72.5 mmHg (cuff closed)	NSD[c]

[a] Faecal incontinence, [b] authors' statistical analysis using Wilcoxon's rank sum test, p values only, no statistics given,
[c] NSD = no significant difference at p>0.05, authors' statistical analysis using Students t-test

As with other outcomes assessed in this report, none of these studies analysed the enrolled patients on an intention-to-treat basis. Data were reported for all enrolled patients for pre-implantation anal manometry measurements in all studies with the exception of AMS (unpublished data 2002) and Wong et al (1996), who reported pre-implantation measurements on 106/112 and 10/12 patients due to the presence of pre-existing stomas. Post-implantation data were reported only for those patients with a successful, functioning ABS.

One study by Vaizey et al (1998a) measured rectal maximum volume and rectal compliance pre- and post-implantation, finding no significant difference between the two measurement time points (Tables 32 and 33).

Table 32 Anal manometry: Rectal maximum volume (ml)

Study	Level of evidence	Quality score	Population	Length of follow-up	Mean value pre-operatively	Mean value post-operatively	Mean difference [95%CI] p value
Vaizey et al (1998a)	IV	1.5	6 female patients with severe FI[a]	Mean follow-up 10 months (range 5-13)	(n=5) mean 144 ± 55.05 cmH_2O	(n=5) mean 131 ± 70.7 cmH_2O	13 ± 42.7 [-39.97, 65.97] p= 0.533

[a] Faecal incontinence

Table 33 Anal manometry: Rectal compliance (ml/cmH_2O)

Study	Level of evidence	Quality score	Population	Length of follow-up	Mean value pre-operatively	Mean value post-operatively	Mean difference [95%CI] p value
Vaizey et al (1998a)	IV	1.5	6 female patients with severe FI[a]	Mean follow-up 10 months (range 5-13)	(n=5) mean 3.98 ± 1.58 cmH_2O	(n=5) mean 4.08 ± 1.89 cmH_2O	0.1 ± 1.33 [-1.55, 1.75] p= 0.87

[a] Faecal incontinence

Length of operating time and hospital stay

Four studies reported length of operating times (Table 34), while five studies reported on the length of hospital stay after ABS implantation (Table 35). Overall, the mean operating time for ABS implantation was 116 ± 35.1 minutes (range 37-250) for 166 patients. The mean post-operative hospital stay ranged from an average of 3.6 to 9 days. The study by AMS (2002) reported patients who required a post-operative stay of between 1 and 59 days.

Table 34 Length of operating time

Study	Level of evidence	Quality score	Population	Length of follow-up	Outcome
Lehur et al (1998)	IV	2.5	13 patients (4 male, 9 female) with severe FI[a]	Median follow-up 30 months (range 5-76)	Mean duration = 130 mins
Altomare et al (2001)	IV	1.5	28 women with severe FI > 1 year	19 months (range 7-41)	Mean duration = 145 mins (range 90-250)
American Medical Systems (unpublished study 2002)	IV	1.5	115 patients with severe FI (29 male, 86 female) Only 112 fitted with device	12 months follow-up	Mean duration = 124 mins (range 37-210)
O'Brien & Skinner(2000)	IV	1.5	13 patients with severe FI (3 male, 10 female)	No follow-up time given	Mean duration = 65 mins

[a] Faecal incontinence

Table 35 Length of hospital stay

Study	Level of evidence	Quality score	Population	Length of follow-up	Outcome
Lehur et al (1998)	IV	2.5	13 patients (4 male, 9 female) with severe FI[a]	Median follow-up 30 months (range 5-76)	Mean post-operative stay = 8 days
Lehur et al (2000)[b]	IV	2.5	24 patients (7 male, 17 female)[b]	Median follow-up 20 months (range 6-35)	Mean post-operative stay = 9 ± 4 days
American Medical Systems (unpublished study 2002)	IV	1.5	115 patients with severe FI (29 male, 86 female) Only 112 fitted with device	12 months follow-up	Mean post-operative stay = 7 days (range 1-59)
O'Brien & Skinner (2000)	IV	1.5	13 patients with severe FI (3 male, 10 female)	No follow-up time given	Mean post-operative stay = 3.6 days
Wong et al (1996)	IV	1.5	12 patients (7 male, 5 female)	Mean follow-up 58 months (range 30-76)	Mean post-operative stay = 7.7 days (range 5-18)

[a] Faecal incontinence, [b] duplication of 4 patients from 1998 in this study

What are the economic considerations?

Due to the poor level of evidence, issues of clinical effectiveness and safety remain unanswered; therefore, an economic analysis was not deemed necessary. A simple costing is provided below.

Dynamic graciloplasty is currently listed on the MBS under items 32203– 32210. Items 32203 and 32206 cover dynamic graciloplasty if the two-step surgical approach is utilised, that is, performing the graciloplasty in one operation, followed by another operation for the insertion of the stimulator and electrodes. The costs of these items are $514.80 and $465.10 respectively. When the graciloplasty and the insertion of the stimulator and electrodes are performed simultaneously the cost is $747.45 and is covered by item number 32209 (Commonwealth Department of Health and Aged Care 2002).

Table 36 indicates the number of services provided for each of the MBS numbers 32203, 32206 and 32209 in Australia in the period between July 2001 and June 2002, and the five year period between July 1997 and June 2002 (Health Insurance Commission 2002). These figures may give some indication of the need, in the Australian setting, for implantation of the ABS.

Table 36 Number of claims processed for dynamic graciloplasty items by MBS

MBS Item Number	Number of services July 2001 to June 2002	Patient demographics	Number of services July 1997 to June 2002	Patient demographics
32203	2	1 female aged 45-54 1 female aged 65-74	26	3 female aged 25-34 1 female aged 35-44 3 female aged 45-54 7 female aged 55-64 3 female aged 65-74 1 female aged 75-84 1 female aged ≥ 85 1 male aged 5-14 3 male aged 45-54 2 male aged 55-64 1 male aged 75-84
32206	3	1 female aged 15-24 2 female aged 55-64	23	1 female aged 0-4 1 female aged 15-24 1 female aged 25-34 3 female aged 35-44 2 female aged 45-54 10 female aged 55-64 2 female aged 65-74 1 male aged 5-14 1 male aged 25-34 1 male aged 55-64
32209	7	1 female aged 35-44 1 female aged 45-54 2 female aged 55-64 1 female aged 65-74 1 male aged 55-64 1 male aged 65-74	33	2 female aged 25-34 4 female aged 35-44 8 female aged 45-54 8 female aged 55-64 4 female aged 65-74 1 male aged 15-24 1 male aged 45-54 3 male aged 55-64 1 male aged 65-74 1 male aged 75-84

Table 37 indicates the costs of the components of the ABS when purchased through private medical insurance.

Table 37 Costs of the ABS and dynamic graciloplasty

Artificial bowel sphincter		Dynamic graciloplasty	
Item	**Cost (A$) excluding GST**	**Item**	**Cost (A$) excluding GST[a]**
ABS cuff	3,000	Pulse generator	6,800
ABS pump	5,600	Leads	5,400
ABS pressure balloon	3,000	Control magnet	90
ABS accessory package	400	Extension (extra)	1,350
(ABS deactivation package)	(400)	Lead (extra)	3,500
		Accessories (extra)	5,000
Total	12,000	Without extras	12,290
		With extras	22,140

[a] August 2000 prices

Conclusions

Safety

Good quality data are not available to assess the safety of artificial bowel sphincter placement in the treatment of faecal incontinence. Poor quality data on follow-up indicate a number of safety issues that need to be addressed. The high explantation rate (30.5%) and high level of adverse events suggests that this procedure can be harmful to the patient. Infection, device malfunction, ulceration and pain are common adverse events, and in many cases they require surgical revision procedures (127 revision procedures were performed on 272 patients). The lack of follow-up is a further concern as there is no information on whether an unsuccessful surgical procedure has a detrimental physical and/or psychological impact on the patient. There is also a lack of long-term safety data and uncertainty surrounds the life expectancy of the device once it is implanted.

Effectiveness

There are no studies available that assess the effectiveness of an artificial bowel sphincter for treating faecal incontinence in comparison to dynamic graciloplasty. Randomised controlled trials in this area are unlikely to be conducted as severe faecal incontinence is a rare condition and the suitable patient population is small. Therefore, only the available case series evidence was assessed. All studies included in this assessment are flawed in their appraisal of outcomes in that patient results are not analysed on an intention-to-treat basis, which may lead to misleading findings in respect to the effectiveness of the procedure. Intention-to-treat is defined as an analysis of all participants, regardless of whether or not they dropped out from the study, did not comply with treatment or received other treatment. The preservation of the patient group as a whole ensures that comparisons can be made and conclusions can be viewed with greater certainty (NHMRC 2000).

From the low-level evidence available, it would appear that for the majority of patients the procedure has uncertain benefits. There is, however, a select group of individuals in whom the procedure has a positive effect on their degree of continence and quality of life. Overall, 68.4 per cent of patients implanted with an ABS have a functioning device at the end of medium-term follow-up. These patients experience an average 62 per cent improvement in their faecal continence levels. The 31.6 per cent of patients with an explanted or non-functioning device did not have outcome data presented. It is possible that ineffective artificial sphincter implantation may have, in fact, worsened the degree of incontinence in these patients. It is therefore crucial that information on these patients is presented so that the degree of benefit or harm can be properly assessed. Methodological deficiencies that need to be addressed include the supply of all short- and long-term outcome data on an intention-to-treat basis, specifically quality of life and continence status, of all patients implanted with an ABS, including explanted patients.

It is clear that patient selection is critical to ensure the safe and effective implantation of the ABS. Case series data can be used to identify more clearly the characteristics of patients who may be best selected for this procedure. These data are currently not

available. Implantation of an ABS is a complex procedure and should be limited to patients suffering severe faecal incontinence who have exhausted all other avenues of conservative medical treatment, such as biofeedback, medical therapy and less rigorous surgery.

Cost-effectiveness

It is not possible to assess the cost-effectiveness of the procedure due to a lack of high quality evidence on clinical effectiveness.

Recommendation

As insufficient evidence pertaining to the safety and effectiveness of the placement of artificial bowel sphincters in the management of faecal incontinence has emerged since this technology was previously considered by the MSAC, the MSAC recommends that public funding should not be supported for this procedure.

The Minister for Health and Ageing accepted this recommendation on August 11, 2003.

Appendix A The MSAC terms of reference and membership

The 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
- under take health technology assessment work referred by the Australian Health Ministers' Advisory Council (AHMAC) and report its findings to AHMAC.

The membership of the 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
Professor Bruce Barraclough	general surgery
Professor Syd Bell	pathology
Dr Paul Craft	clinical epidemiology and oncology
Associate Professor Jane Hall	health economics
Dr Terri Jackson	health economics
Ms Rebecca James	consumer health issues
Professor Brendon Kearney	health administration and planning
Associate Professor Richard King	internal medicine
Dr Ray Kirk	health research
Dr Michael Kitchener	nuclear medicine
Mr Lou McCallum	consumer health issues
Dr Ewa Piejko	general practice
Mr Chris Sheedy	Assistant Secretary, Diagnostics and Technology Branch, Commonwealth Department of Health and Ageing
Professor John Simes	clinical epidemiology and clinical trials

Professor Richard Smallwood	Chief Medical Officer, Commonwealth Department of Health and Ageing
Professor Bryant Stokes	neurological surgery, representing the Australian Health Ministers' Advisory Council
Associate Professor Ken Thomson	radiology
Dr Douglas Travis	urology

Appendix B The MSAC supporting committee

Supporting committee for the MSAC application 1053
Placement of artificial bowel sphincters in the management of faecal incontinence

Professor Bryant Stokes AM (Chair) MBBS, FRACS, FRCS Chief Medical Officer Health Department of Western Australia	member of the MSAC
Associate Professor David Fonda MBBS, B.Med Sc, FRACP, FACRM Geriatrician and Continent Specialist Aged Care Services Caulfield General Medical Centre Caulfield, Victoria	Australian Society for Geriatric Medicine Association
Dr David Jarvis MBChB, FRACGP, BA, BLitt General Practitioner Jamison Centre, Australian Capital Territory	Royal Australian College of General Practitioners
Professor David Lubowski MBcHB, FRACS Colorectal Surgeon St George Hospital, Sydney New South Wales	Colorectal Surgical Society
Associate Professor Michael Solomon MSc, MBBCh, FRACS, LRCSI, LRCPI Colorectal Specialist Surgeon Royal Prince Alfred Hospital Medical Centre Sydney, New South Wales	Royal Australasian College of Surgeons
Ms Elizabeth Symons RN, GradDip AE&T, PgradDipEval, MRCNA Stomal Therapy Nurse Continence Nurse Adviser	Consumer Representative

Appendix C Studies included in the review

Study profiles of included studies on prevalence

Prevalence in the community

Study	Location	Study design	Study population	Prevalence of incontinence	
Bytzer et al (2001)	Sydney, Australia	Cross-sectional survey Postal questionnaire	15,000 randomly selected adults on the Australian electoral roll 8,657 (57.7%) completed and returned	Controls Diabetics Total	65/8185 (0.8%) 11/423 (2.6%) 76/8608 (0.9%)
Kalantar et al (2002)	Sydney, Australia	Cross-sectional survey Postal Questionnaire	990 randomly selected adults on the Australian electoral roll in Western Sydney 642 (65%) completed and returned	Faecal incontinence Incontinent to: Liquid stool Formed stool	72/642 (11.2%) 58/642 (9.0%) 13/642 (2.0%)
Lam et al (1999)	Sydney, Australia	Cross-sectional survey Postal Questionnaire	955 randomly selected adults on the Australian electoral roll in Southern Sydney 618 (62%) completed and returned	Faecal incontinence: Total Female Female ≥ 65 Female < 65 Male Male ≥ 65 Male < 65	 92/618 (14.9%) 40/359 (11.1%) (14.3%) (9.6%) 52/259 (20%) (20%) (20%)
MacLennan et al (2000)	South Australia, Australia	Cross-sectional survey Interviewed in participants homes	4,400 randomly selected South Australian adults (>15 years) as part of the South Australian Health Omnibus Survey 3,010/4,400 interviewed (73.3%)	Faecal incontinence: Total Male Female Flatus incontinence: Total Male Female	 3,010 (2.9%) 33/1,464 (2.3%) 54/1,546 (3.5%) 268/3,010 (8.9%) 100/1,464 (6.8%) 168/3,010 (5.6%)

Drossman et al (1993)	USA	Cross sectional survey	5,430 respondents to a questionnaire. Random mail out generated from a household database	Functional incontinence: Total Male Female Age 15-34 Age 35-44 Age > 45 Faecal soiling: Total Male Female Age 15-34 Age 35-44 Age >45 Gross incontinence: Total Male Female Age 15-34 Age 35-44 Age >45	 424/5,430 (7.8%) 208/2,639 (7.9%) 215/2,791 (7.7%) 68/1,199 (5.7%) 82/1,289 (6.4%) 266/2,894 (9.2%) 388/5,430 (7.1%) 195/2,639 (7.4%) 193/2,791 (6.9%) 66/1,199 (5.5%) 80/1,289 (6.2%) 237/2,894 (8.2%) 36/5,430 (0.7%) 13/2,639 (0.5%) 25/2,791 (0.9%) 2/1,199 (0.2%) 3/1,289 (0.2%) 29/2,894 (1.0%)
Edwards & Jones (2001)	United Kingdom	Cross-sectional survey Questionnaire	3,000 people randomly selected from Health Service registers, ≥65 years of age 2,794 (93.1%) completed and returned	Total Male Female	78/2,794 (2.79%) 15/1,084 (1%) 63/1,632 (4%)
Faltin et al (2001	Geneva, Switzerland	Cross-sectional survey Questionnaire	984 randomly selected women from the general population 35-74 years	Anal incontinence	43/984 (4.4%)
Lynch et al (2001)	Christchurch, New Zealand	Cross-sectional survey Postal questionnaire	1,500 randomly selected adults on the New Zealand electoral roll in Canterbury 717 (48%) completed and returned	Faecal incontinence Male Female	118/717 (16.5%) 67/388 (17.3%) 51/329 (15.5%)
Nakanishi et al (1997)	Osaka, Japan	Population-based cross-sectional survey In-home interviews	1,473 randomly selected people >65 years from the computerised sex–age register 1,405/1,473 (95.4%) interviewed	Faecal incontinence: ≥ Daily ≤ Daily	 5/1,405 (3.56%) 25/1,405 (1.78%)

Nelson et al (1995)	Wisconsin, USA	Population based cross-sectional survey Telephone interview	4,446 households selected through random digit dialling 2,570/4,446 households surveyed (73%) 6,569 individuals interviewed	Anal incontinence	153/6,569 (2.3%)
Perry et al (2002)	Leicestershire, England	Cross-sectional survey Postal questionnaire	15,904 individuals >40 years randomly selected by household from the Leicestershire Health Authority 10,116/14,600 (69.3%) returned and completed	Faecal incontinence (1.4%) Age 40-64 yrs Age 65+ yrs	142/10,116 0.9% 2.3%
Roberts et al (1999)	Olsmet County, Minnesota, USA	Cross-sectional survey Self-administered questionnaire	2,400 subjects ≥50 years selected randomly from the Rochester Epidemiology Project 1,540/2,337 (65.9%) completed and returned questionnaire	Faecal incontinence Total (13.1%) Male Female	 202/1,540 88/778 (11%) 114/762 (15%)
Talley et al (1992)	Olsmet County, Minnesota, USA	Cross-sectional survey Postal survey	500 subjects ≥65 years randomly sampled from attendees at Mayo Clinic 1987-1990 328/500 (66%) completed and returned questionnaire	Incontinence of stool	12/328 (3.7%)

Prevalence in pregnant and post-partum women

Abramowitz et al (2000)	Paris, France	Consecutive series pregnant women Assessment: questionnaire followed up by endosonography in the last 3 months of gestation and between the 6th and 8th week post-partum	259 pregnant women 118 primiparous 63 secundiparous 52 multiparous Total 26 (10%) lost to follow-up	Pre-delivery Post-delivery Pre-delivery Post-delivery Pre-delivery Post-delivery Pre-delivery Post-delivery	1/118 (0.8%) 15/118 (12.7%) 3/63 (4.7%) 13/63 (20.6%) 4/52 (7.6%) 3/52 (5.77%) 15/233 (6.4%) 32/233 (13.7%)
Chaliha et al (2001)	London, United Kingdom	Consecutive series pregnant women Assessment: questionnaire followed up by endosonography and manometry at 34 weeks gestation and 12 weeks post-partum	549 consecutive nulliparous women 286 women agreed to endosonography 161 women attended both pre- and post-delivery examinations 125 (22.8%) lost to follow-up	Before pregnancy Pre-delivery Post-delivery	3/161 (1.86%) 15/161 (9.3%) 21/161 (13%)
Crawford et al (1993)	Michigan, USA	Consecutive series pregnant women	35 consecutive nulliparous women with rupture of the anal sphincter 35 consecutive nulliparous women without rupture	Incontinent to Flatus Liquid stool Formed stool Incontinent to Flatus Liquid stool Formed stool	 6/35 (17%) 1/35 (3%) 1/35 (3%) 1/35 (3%) 1/35 (3%) 0/35 (0%)
Donnelly et al (1998)	Dublin, Ireland	Prospective cohort of pregnant women Questionnaire 6 weeks post-partum	184 primiparous women	Caesarean Vaginal delivery Instrument delivery Total	0/16 (0%) 2/146 (1.4%) 5/22 (23%) 7/184 (3.8%)

Eason et al (2002)	Ottawa, Canada	Prospective cohort of pregnant women Questionnaire 3 months post-partum	948 pregnant women	Incontinent (stool) Caesarean Vaginal delivery Incontinent (flatus) Caesarean Vaginal delivery	29/948 (3.1%) 2/114 (1.8%) 27/ 834 (3.23%) 242/948 (25.5%) 26/114 (22.8%) 216/834 (25.9%)
Faltin et al (2001)	Geneva, Switzerland	Prospective cohort of pregnant women Questionnaire 3 and 30 months post-partum	92 nulliparous women who delivered vaginally	Incontinent At 3 months (first child) At 30 months First child only Second child	 16/92 (17.4%) 11/77 (14.3%) 5/54 (9.25%) 6/23 (26.1%)
Faltin et al (2001	Geneva, Switzerland	Consecutive series of women attending Obstetrics and Gynaecology outpatients Questionnaire	1,435 consecutive women attending outpatients clinics 1,228 (85.6%) returned questionnaire	Anal incontinence	99/1,228 (8.1%)
Fornell et al (1996)	Linköping, Sweden	Consecutive series pregnant women Questionnaire administered 6 months post-partum	51 consecutive women with rupture of the anal sphincter 31 consecutive women without rupture	Incontinent to Flatus Liquid stool Formed stool Flatus Liquid stool Formed stool	 12/51 (24%) 8/51 (16%) 0/51 (0%) 10/31 (32%) 4/31 (13%) 0/31 (0%)
Groutz et al (1999)	Tel Aviv, Israel	Consecutive series patients Telephone questionnaire administered 3 months post-partum	300 unselected consecutive pregnant women	Anal incontinence Primiparous Multiparous Vaginal delivery Assisted delivery Caesarean	21/300 (7.0%) 13/21 (61.9%) 8/21 (38.1%) 9/21 (42.86%) 11/21 (52.38%) 1/21 (4.76%)
Højberg et al (2000)	Denmark	Cross-sectional survey Questionnaire	7557 pregnant women at 16 weeks gestation Parity 0	Anal incontinence Incontinent Flatus Liquid stool Formed stool Anal incontinence Incontinent Flatus Liquid stool Formed stool	649/7,557 (8.6%) 446/7,557 (5.9%) 100/7,557 (1.3%) 16/7,557 (0.2%) 321/3,991 (8.0%) 209/3,991 (5.2%) 60/3,991 (1.6%) 10/3,991 (0.2%)

			Parity 1	Anal incontinence Incontinent Flatus Liquid stool Formed stool	241/2,554 (9.4%) 170/2,554 (6.7%) 36/2,554 (1.4%) 5/2,554 (0.2%)
			Parity ≥2	Anal incontinence Incontinent Flatus Liquid stool Formed stool	87/1,012 (8.6%) 67/1,012 (6.7%) 4/1,012 (0.4%) 1/1,012 (0.1%)
MacArthur et al (2001)	Aberdeen, Scotland; Birmingham, England; Dunedin, New Zealand	Consecutive series women Postal questionnaire	10,989 women at 3 months post-partum 7,879/10,989 (71.7%) completed and returned Total	Incontinent (stool) *Rarely* *Sometimes* *Often* *Always* Incontinent (flatus) *Rarely* *Sometimes* *Often* *Always*	 392/7,275 (5.4%) 249/7,275 (3.42%) 38/7,275 (0.5%) 20/7,275 (0.3%) 1461/7,788 (19%) 1566/7,788 (20%) 410/7,788 (5.3%) 90/7,788 (1.2%)
			Primiparous	Incontinent (stool) *Rarely* *Sometimes* *Often* *Always* Incontinent (flatus) *Rarely* *Sometimes* *Often*	 178/3,261 (5.5%) 95/3,261 (2.9%) 14/3,261 (0.4%) 7/3,261 (0.2%) 635/3,457 (18.4%) 657/3,457 (19.0%) 178/3,457 (5.1%)
			Multiparous	Incontinent (stool) *Rarely* *Sometimes* *Often* *Always* Incontinent (flatus) *Rarely* *Sometimes* *Often* *Always*	 208/3,893 (5.3%) 151/3,893 (3.9%) 24/3,893 (0.6%) 13/3,893 (0.3%) 799/4,202 (19.0%) 877/4,202 (20.9%) 227/4,202 (5.4) 58/4,202 (1.4%)

Rizk et al (2001)	Al-Ain, United Arab Emirates	Community-based survey	450 multiparous women 225 multiparous randomly selected women from primary health care centres 225 multiparous randomly selected women from community	Faecal incontinence Incontinent to Liquid stool Solid stool Flatus	51/450 (11.3%) 26/450 (5.8%) 25/450 (5.5%) 65/450 (14.4%)
Sultan et al (1993)	London, United Kingdom	Consecutive series women Questionnaire at 34 weeks gestation and 6-8 weeks post-partum	202 consecutive women 150/202 (74.2%) returned for post-partum assessment 100 primiparous women, 79/100 vaginal delivery 50 multiparous women, 48/50 vaginal delivery	Post-partum Incontinent to Liquid stool Flatus 34 weeks gestation Incontinent to Liquid stool Flatus Post-partum Incontinent to Liquid stool Flatus	 1/79 (1.3%) 3/79 (3.8%) 5/48 (10.4%) 3/48 (6.25%) 4/48 (8.3%) 4/48 (8.3%)
Varma et al (1999)	Hull, United Kingdom	Consecutive series women Questionnaire 1 month post-partum	159 consecutive women 54 primiparous 39/54 (72%) questionnaires returned and completed 105 secundiparous 76/105 (72%) questionnaires returned and completed	Faecal incontinence Faecal incontinence	0/39 (0%) 0/76 (0%)

Zetterström et al (1999)	Stockholm, Sweden	Prospective Cohort of pregnant women Questionnaire pre-partum, 5 and 9 months post-partum	438 nulliparous women Exclusions (n=89): twins, caesarian and non-Swedish speakers Pre-partum 309/349 (89%) 5 months post-partum 287/349 (82%) 9 months post-partum 278/349 (80%) completed and returned questionnaires	Faecal incontinence Flatus Faecal incontinence Flatus Faecal incontinence Flatus	2/278 (0.7%) 20/278 (7.2%) 5/278 (1.8%) 70/278 (25.2%) 3/278 (1.1%) 71/278 (25.5%)

Prevalence in nursing home residents

Chassagne et al (1999)	France	Prospective Cohort	2,602 residents of nursing homes aged over 60	Faecal incontinence (49%)	1,275/2,602
Johanson et al (1997)	Illinois, USA	Cross-sectional survey Questionnaire	388 nursing home residents	Faecal incontinence Male Female Incontinent (liquid stool) Male Female Incontinent (formed stool) Male Female	177/388 (45.6%) 59/93 (63%) 118/295 (48%) 30/93 (32.5%) 71/295 (24%) 41/93 (44%) 66/295 (22.5%)
Nelson et al (1998)	Wisconsin, USA	Cross-sectional survey Assessment of nursing home residents by trained professionals	1992 study 181/390 (46.4%) nursing homes provided data 18,224 residents 1993 Study 177/390 (45.4%) nursing homes provided data 17,127 residents	Faecal incontinence: Total Male Female Faecal incontinence: Total Male Female	 8,471/18,224 (47%) 2,457/5,285 (46.5%) 6,014/12,939 (46.5%) 7,860/17,127 (46%) 2247/4,796 (46.9%) 5,613/12,331 (45.5%)
Peet et al (1995)	Leicestershire, UK	Cross-sectional survey	6,079 nursing home residents 5,758/6,079 (95%) participated	Faecal incontinence	179/5,758 (3.1%)

Prevalence in multiple sclerosis patients

Bakke et al (1996)	Bergen, Norway	Prospective cohort Assessed by the Incapacity Status Scale (ISS)	208 multiple sclerosis patients (all MS patients living in Western Norway)	Faecal incontinence	7/208 (3.4%)
Chia et al (1995)	London, United Kingdom	Consecutive series of multiple sclerosis patients Questionnaire	77 consecutive MS patients attending a urology clinic	Faecal incontinence	12/77 (15.58%)

Prevalence in urinary incontinent women

Gordon et al (1999)	Tel Aviv, Israel	Consecutive series women Questionnaire	283 urinary incontinent women	Anal incontinence Incontinent to Flatus Liquid stool Formed stool	83/283 (29.3%) 40/283 (14.1%) 18/283 (6.4%) 25/283 (8.8%)
Khullar et al (1998)	London, United Kingdom	Consecutive series women Questionnaire	465 consecutive women attending urodynamic clinic 183/465 with urinary incontinence	Faecal incontinence Faecal incontinence	41/465 (8.8%) 30/183 (16.4%)
Leroi et al (1999)	Rouen, France	Consecutive series women Questionnaire	450 consecutive women with stress urinary incontinence attending urodynamic clinic 409 (91%) completed and returned questionnaire	Faecal incontinence Incontinent to Flatus Liquid stool Formed stool	114/409 (28%) 75/409 (18.3%) 39/409 (9.5%) 5/409 (1.0%)

Study profiles of included studies on safety and effectiveness

Level of evidence	Quality score	Study	Location	Study design	Study population	Outcome(s) assessed	Length of follow-up
IV	1.5 /3	Altomare DF Dodi G La Torre F Romano G Melega E Rinaldi M (2001)	Padua Bari, Naples and Rome, Italy	Case series	28 female patients with severe FI[a] Cause(s) of FI: Idiopathic = 14 Obstetric = 6 Neurological = 4 Iatrogenic = 3 Congenital = 1 Eligibility criteria: affected with FI for more than 1 year	Faecal incontinence QOL[b] Adverse events Explantation Anal manometry: resting anal and squeeze pressure	Median follow-up 19 months (range 7-41)
IV	1.5/3	American Medical Systems (unpublished study) [A] published by Wong et al (2002)	USA, Canada, France and Spain	Multi-centre case series	115 patients (29 male, 86 female) only 112 patients fitted with device Cause(s) of FI[a]: Obstetric = 34 Neurological = 23 Congenital = 23 Anorectal Trauma = 21 Other = 14 Eligibility criteria: FI score ≥ 88[e] and affected with FI for more 6 months. Post-pubescent patients.	Faecal Incontinence QOL[b] assessment Adverse events Explantation Anal manometry: resting anal pressure	12 months

IV	1.5/3	Christiansen J Rasmussen OØ Lindorff-Larsen K (1999)	Copen-hagen, Denmark	Case series	17 patients (11 female, 6 male) with FI[a] Cause(s) of FI: Neurological = 10 Anal atresia = 1 Previously failed surgery for FI = 6 Eligibility criteria: FI with a Williams incontinence score of 5[d]	Continence score Adverse events Explantation	≥ 5 years
IV	1.5/3	Dodi G Melega E Masin A Infantino A Cavallari F Lise M (2000)	Padova, Italy	Case series	8 female patients Cause(s) of FI[a]: Idiopathic = 6 Congenital = 1 Traumatic = 1 Eligibility criteria: severe FI	Continence score Adverse events Explantation Anal manometry: resting anal and squeeze pressure	Mean follow-up 10.5 months (range: 4-23)
n.a.	n.a.	Gelet a Meunier P Lombard Platet R AbdelRahim AF Friaa S Lopez JG Manzan K Dubernard JM (1997)	Lyon, France	Case report	1 female patient with dual faecal and urinary incontinence	Faecal incontinence Adverse events Anal manometry: resting anal and squeeze pressure	2 years
IV	2.5/3	Lehur PA Glemain P Bruley des Varannes S Buzelin JM Leborgne J (1998)	Nantes and Rouen, France	Case series	13 consecutive patients (4 male, 9 female) Cause(s) of FI[a]: Anal atresia = 3 Neurologic = 2 Obstetric = 1 Sequelae of surgery = 6 Idiopathic = 1 Eligibility criteria: FI[a] for median 15 years (range 3-28)	Faecal incontinence scores Adverse events Explantation Anal manometry: resting anal pressure	Median follow-up 30 months (range: 5-76)

IV	2.5/3	Lehur PA Roig JV Duinslager M (2000) Duplication of 4 patients from 1998 study	Nantes, France; Sagunto, Spain; and Brussels, Belgium	Case series	24 consecutive patients (7 male, 17 female) Cause(s) of FI [a]: Anal trauma = 6 Idiopathic = 6 Anal trauma + idiopathic = 3 Neurologic = 4 Anal agenesia = 3 Rectal prolapse =2 Eligibility criteria: severe FI[a] for median 7.5 years, (range 1-33)	Faecal incontinence scores Adverse events Explantation Anal manometry: resting anal pressure	Median follow-up 20 months (range: 10-35)
IV	2.5/3	Lehur PA Zerbib F Neunlist M Glemain P Bruley des Varannes S (2002) Some duplication of patients from 1998 and 2000 studies	Nantes, France	Case series	16 consecutive patients (2 male, 14 female) Cause(s) of FI[a]: Anal trauma = 5 Pudendopathy =2 Anal trauma + pudendopathy = 2 Neurologic = 2 Anal agenesia = 3 Rectal prolapse =2 Eligibility criteria: severe FI[a] for median 1 year, (range 1-33)	Faecal incontinence scores Adverse events Explantation Anal manometry: Resting anal pressure QOL[b] assessment	Mean follow-up 25 months (range 7-49)
IV	1.5/3	O'Brien PE Skinner S (2000)	Melbourne, Australia	Case series	13 patients (3 male, 10 female) Cause(s) of FI[a]: Obstetric injury = 8 Congenital = 2 Spina Bifida = 1 Anal surgery = 2 Eligibility criteria: Severe FI[a] for average 12.7 years	Faecal incontinence scores Adverse events Explantation QOL[b] assessment	No follow-up time period given

IV	1.5/3	Ortiz H Armendariz P DeMiguel M Ruiz MD Alós R Roig JV (2002)	Sagunto, Spain	Case series	22 patients (5 male, 17 female) Cause(s) of FI[a]: Obstetric injury = 8 Congenital = 2 Spina Bifida = 1 Sequelae of anal surgery = 2 Eligibility criteria: severe FI [a] for average 18 years (range 2-39)	Faecal incontinence scores Adverse events Explantation Anal manometry: resting anal pressure	Mean follow-up 28 months (range 6-48)
IV	1.5/3	Vaizey CJ Kamm MA Gold DM Bartram CI Halligan S Nicholls RJ (1998)	London, United Kingdom	Case series	6 female patients Cause(s) of FI[a]: Obstetric = 1 Obstetric + lateral sphincterotomy = 2 Idiopathic = 2 Congenital = 1 Eligibility criteria: faecal incontinence for median 20 years (range 4-40) and failure of previous surgical treatment	Faecal incontinence scores Adverse events Explantation Anal manometry: resting anal pressure Maximum volume Rectal compliance	Median follow-up 10 months (range 5-13)
IV	1.5/3	Wong WD Jensen LL Bartolo DCC Rothenberger DA (1996)	Minneapolis, USA and Edinburgh, Scotland	Case series	12 patients (7 male, 5 female) Cause(s) of FI[a]: Obstetric = 4 Major trauma = 3 Imperforate anus = 2 Congenital = 1 Other = 2 Eligibility criteria: faecal incontinence and failure of conventional treatment	Adverse events Explantation Anal manometry: resting anal pressure	Mean follow-up 58 months (range 30-76)

[a] FI = faecal incontinence, [b] QOL = quality of life, [c] AAS = artificial anal sphincter, [d] Williams incontinence scale 1 to 5 (1 = full continence, 5 = frequent episodes of incontinence to solid and liquid stool), [e] AMS Faecal incontinence scoring system 0 to 120 (0 = full continence, 120 = incontinent to liquids or solids > daily)

1. A recent study by Devesa et al (2002) published in October has not been included for analysis in this report. This study was a case series of 53 patients and outcomes of this study were not analysed on an intention-to-treat basis. The results of this study would not alter the outcome of this report

Appendix D Search strategies

Searching on treatment of faecal incontinence

#1	explode "Fecal-Incontinence" / all SUBHEADINGS
#2	explode "Anus" / all SUBHEADINGS
#3	explode "Prostheses-and-Implants" / all SUBHEADINGS
#4	#1 or #2 or #3
#5	anal and incontinen*
#6	f?ecal near incontinen*
#7	(artificial or acticon or cuff or balloon) and (anal or bowel or sphincter)
#8	gracilo?plas*
#9	#5 or #6 or #7 or #8
#10	#9 not (urin* or urethr* or achalasia or oesophag* or esophag*)
#11	#4 not (urin* or urethr* or achalasia or oesophag* or esophag*)
#12	#10 and #11
#13	tg = animal
#14	tg = human
#15	#13 not (#13 and #14)
#16	#12 not #15
#17	#16 and (english in la)

Searching on prevalence of faecal incontinence

#1	explode "Fecal-Incontinence" / all SUBHEADINGS in MIME,MJME
#2	explode "Anus" / all SUBHEADINGS in MIME,MJME
#3	#1 or #2
#4	anal and incontinen*
#5	f?ecal near incontinen*
#6	#4 or #5
#7	#6 not (urin* or urethr* or achalasia or oesophag* or esophag*)
#8	#3 not (urin* or urethr* or achalasia or oesophag* or esophag*)
#9	explode "Prevalence" / WITHOUT SUBHEADINGS in MIME,MJME
#10	explode "Cross-Sectional-Studies" / WITHOUT SUBHEADINGS in MIME,MJME
#11	explode "Incidence" / WITHOUT SUBHEADINGS in MIME,MJME
#12	explode "Cohort-Studies" / WITHOUT SUBHEADINGS in MIME,MJME
#13	explode "Epidemiology" / all SUBHEADINGS in MIME,MJME
#14	explode "Natural-History" / all SUBHEADINGS in MIME,MJME
#15	explode "Risk" / all SUBHEADINGS in MIME,MJME
#16	explode "Population-Characteristics" / all SUBHEADINGS in MIME,MJME
#17	risk* or epidemiol* or inciden* or natural histor* or cohort or population or registry or register
#18	#9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17
#19	#7 and #18
#20	#8 and #18
#21	#19 or #20
#22	tg = animal
#23	tg = human
#24	#22 not (#22 and #23)

#25	#21 not #24
#26	#25 and (english in la)

Appendix E Health technology assessment internet sites

GENERAL

The following general databases of health technology assessment reports were searched up until 8/2002

- International Society of Technology Assessment in Health Care http://www.istahc.org/en/welcome.html
- International Network for Agencies for Health Technology Assessment http://www.inahta.org/ [the same HTA database that is held in Cochrane and University of York]
- National Library of Medicine Health Services / Technology Assessment Text http://text.nlm.nih.gov/
- National Library of Medicine Locator Plus database http://locatorplus.gov

More recent listings of reports will be located and searched at the websites of health technology assessment agencies up until 8/2002

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/
- Health Economics Unit, 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/index.htm
- Alberta Heritage Foundation for Medical Research (AHFMR) http://www.ahfmr.ab.ca/publications.html
- Canadian Coordinating Office for Health Technology Assessment (CCOHTA) http://www.ccohta.ca/newweb/pubapp/pubs.asp
- 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

DENMARK

- Danish Institute for Health Technology Assessment (DIHTA) http://www.dihta.dk/publikationer/index_uk.asp

FINLAND

- 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.dahta.dimdi.de/
- German Scientific Working Group of Technology Assessment http://www.epi.mh-hannover.de/(eng)/hta.html

THE NETHERLANDS

- Health Council of the Netherlands Gezondheidsraad http://www.gr.nl/engels/welcome/frameset.htm

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/aets/cdoc.htm

- Catalan Agency for Health Technology Assessment (CAHTA) http://www.aatm.es/cgi-bin/frame.pl/ang/pu.html

SWEDEN

- Swedish Council on Technology Assessment in Health Care (SBU) http://www.sbu.se/admin/index.asp

SWITZERLAND

- Swiss Network on Health Technology Assessment (SNHTA) http://www.snhta.ch/

UNITED KINGDOM

- Health Technology Board for Scotland http://www.htbs.org.uk/
- National Health Service Health Technology Assessment (UK) / National Coordinating Centre for Health Technology Assessment (NCCHTA) http://www.hta.nhsweb.nhs.uk/
- University of York NHS Centre for Reviews and Dissemination (NHS CRD) http://www.york.ac.uk/inst/crd/
- National Institute for Clinical Excellence (NICE) http://www.nice.org.uk/index.htm

UNITED STATES

- Agency for Healthcare Research and Quality (AHRQ) http://www.ahrq.gov/clinic/techix.htm
- Harvard Center for Risk Analysis – Cost-Utility Analysis Database Project [comprehensive league table] http://www.hcra.harvard.edu/tablesdata.html
- U.S. Blue Cross/ Blue Shield Association Technology Evaluation Center (TEC) http://www.bcbs.com/consumertec/index.html
- U.S. Dept. of Veterans Affairs Technology Assessment Program (VATAP) http://www.va.gov/resdev/prt/pubs_individual.cfm?webpage=pubs_ta_reports.htm

Appendix F Studies excluded from the review

Data included in other studies:

Christiansen, J. & Lorentzen, M. (1987). 'Implantation of artificial sphincter for anal incontinence', *The Lancet,* 2 (8553), 244-245.

Christiansen, J. & Lorentzen, M. (1989). 'Implantation of artificial sphincter for anal incontinence. Report of five cases', *Diseases of the Colon and Rectum,* 32 (5), 432-436.

Christiansen, J. & Sparso, B. (1992). 'Treatment of anal incontinence by an implantable prosthetic anal sphincter', *Annals of Surgery,* 215 (4), 383-386.

Lehur, P. A., Michot, F. et al. (1996). 'Results of artificial sphincter in severe anal incontinence. Report of 14 consecutive implantations', *Diseases of the Colon and Rectum,* 39 (12), 1352-1355.

Savoye, G., Leroi, A. M. et al. (2000). 'Manometric assessment of an artificial bowel sphincter', *British Journal of Surgery,* 87 (5), 586-589.

Prosthesis used was not AMS, Acticon™ Neosphincter or ABS:

Bachoo, P., Brazzelli, M. and Grant, A. (2002) *Surgery for faecal incontinence in adults,* The Cochrane Library, Issue 1, Oxford: Update Software.

Hajivassiliou, C. A. & Finlay, I. G. (1998). 'Effect of a novel prosthetic anal neosphincter on human colonic blood flow', *British Journal of Surgery,* 85 (12), 1703-1707.

Heiblum, M. & Cordoba, A. (1978). 'An artificial sphincter: a preliminary report', *Diseases of the Colon and Rectum,* 21 (8), 562-566.

Lee, S. L., DuBois, J. J. et al. (2002). 'Surgical management of chronic unremitting constipation and fecal incontinence associated with megarectum: A preliminary report', *Journal of Pediatric Surgery,* 37 (1), 76-79.

MSAC (1999). *Placement of artificial bowel sphincters in the management of faecal incontinence,* Medical Services Advisory Committee, Canberra.

Prophet, S. (2002). 'ICD-9 Committee explores new technology, drug codes', *Journal of American Health Information Management Association,* 73 (4), 64-69.

Non-English articles:

Ruppert, P. & Staimmer, D. (1998). 'Fecal incontinence--new surgical treatments. ABS-artificial bowel sphincter', *Krankenpflege Journal,* 36 (10), 376-378.

Preliminary report:

Malouf, A. J., Vaizey, C. J. et al. (2000). 'Reassessing artificial bowel sphincters', *The Lancet,* 355 (9222), 2219-2220.

Narrative review articles:

Christiansen, J. (1992a). 'Advances in the surgical management of anal incontinence', *Bailliere's Clinical Gastroenterology,* 6 (1), 43-57.

Christiansen, J. (1992b). 'Advances in the surgical management of anal incontinence (plus discussion)', *Memoires. Academie de Chirurgie (France),* 118 (5), 277-282; discussion 282-283.

Christiansen, J. (1998). 'Modern surgical treatment of anal incontinence', *Annals of Medicine,* 30 (3), 273-277.

Christiansen, J. (2000). 'The artificial anal sphincter', *Canadian Journal of Gastroenterology,* 14 Suppl D, 152D-154D.

Lehur, P. A. (1999a). 'The anal artificial sphincter in severe anal incontinence', *International Journal of Surgical Investigation,* 1 (3), 268-269.

Madoff, R. D., Baeten, C. G. et al. (2000). 'Standards for anal sphincter replacement', *Diseases of the Colon and Rectum,* 43 (2), 135-141.

Michot, F., Lehur, P. A. & Forestier, F. (1997). 'Artificial anal sphincter', *Seminars in Colon and Rectal Surgery,* 8 (2), 116-120.

Niriella, D. A. & Deen, K. I. (2000). 'Neosphincters in the management of faecal incontinence', *British Journal of Surgery,* 87 (12), 1617-1628.

Vaizey, C. J., Kamm, M. A. & Nicholls, R. J. (1998). 'Recent advances in the surgical treatment of faecal incontinence', *British Journal of Surgery,* 85 (5), 596-603.

Letters:

Anonymous (2002). 'Frequent faecal incontinence', *Medicine Today,* 3 (3), 10.

Hajivassiliou, C. A. & Finlay, I. G. (1997). 'Artificial anal sphincter', *Diseases of the Colon and Rectum,* 40 (10), 1261.

Hoogerwerf, W. A. & Pasricha, P. J. (1999). 'Taking control of fecal incontinence: early results of an artificial sphincter device', *Gastroenterology,* 116 (4), 1005-1006.

Lehur, P. A. (1998). 'Artificial anal sphincter', *Diseases of the Colon and Rectum,* 41 (9), 1201.

Lehur, P. A. (1999b). 'Effect of a novel prosthetic anal neosphincter on human colonic blood flow', *British Journal of Surgery,* 86 (8), 1096-1097; discussion 1097-1098.

Mander, B. J. & Williams, N. S. (1996). 'Patient selection is integral to the success of the electrically stimulated gracilis neosphincter', *Diseases of the Colon and Rectum,* 39 (6), 712-713.

Narasimhan, K. L. (1993). 'Treatment of anal incontinence by an implantable prosthetic anal sphincter', *Annals of Surgery,* 217 (3), 308.

Appendix G Critical appraisal checklists

Checklist for the critical appraisal of case series

Source: Young et al (1999). *Lung volume reduction surgery (LVRS) for chronic obstructive pulmonary disease (COPD) with underlying severe emphysema.* A West Midlands Development and Evaluation Committee Report, University of Birmingham, p51-53.

Title of review:
Title of study:

Author(s):
Year:
Comparators:
Score: **/3**

1. **Was the study conducted prospectively?** **/1**

- Were the key outcomes measured before and after the intervention, using clear criteria defined *a priori*?

2. **Was the method of selection of cases identified and appropriate?** **/1**

- Were patients selected consecutively or in an unbiased manner?

- Was there evidence that the characteristics of the included cases were not significantly different from those of the treated population?

3. **Was the duration and completeness of follow-up reported and was it adequate?**

- Are the number and characteristics of losses to follow-up presented? [#] **/0.5**

- Are losses to follow-up managed by performing sensitivity analysis and/or including them in the final analysis? **/0.5**

[#] Losses to follow-up >20% are unacceptable, particularly if unaccounted for.

Appendix H Faecal incontinence scoring systems

American Medical Systems faecal incontinence scores definition

FI Value	Definition
0	Fully continent
1-30	Incontinent to gas
31-60	Incontinent to seepage
61-72	Incontinent to liquids or solids rarely
73-84	Incontinent to liquids or solids > monthly
85-96	Incontinent to liquids or solids > weekly
97-108	Incontinent to liquids or solids daily
109-120	Incontinent to liquids or solids > daily

Source: AMS (2002)

Cleveland Clinic 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

20 points = complete incontinence, 0 points = perfect continence
Source: Jorge & Wexner (1993)

Modified Williams scale

FI Value	Definition
1	Continent to solids, liquids and flatus
2	Continent to solids and liquids but not to flatus
3	Continent to solids, occasional incontinence to liquids
4	Occasional episodes of incontinence to liquids
5	Frequent episodes of incontinence to liquids and solids

Source: Christiansen et al (1999)

Abbreviations

ABS	artificial bowel sphincter
AHMAC	Australian Health Ministers Advisory Committee
AMS	American Medical Systems
FIQL	faecal incontinence quality of life scale
HSQ 2.0	health status questionnaire
MBS	Medicare Benefits Schedule
MSAC	Medical Services Advisory Committee
NHMRC	National Health and Medical Research Council
QOL	quality of life
SF-36	short form-36 questionnaire

References

Abramowitz, L., Sobhani, I. et al (2000). 'Are sphincter defects the cause of anal incontinence after vaginal delivery? Results of a prospective study', *Diseases of the Colon and Rectum,* 43 (5), 590-596.

Altomare, D. F., Dodi, G. et al (2001). 'Multicentre retrospective analysis of the outcome of artificial anal sphincter implantation for severe faecal incontinence', *British Journal of Surgery,* 88 (11), 1481-1486.

American Medical Systems (A M S) (unpublished data 2002). 'American Medical Systems' Prospective Clinical Study'.

Anonymous (2002). 'Frequent faecal incontinence', *Medicine Today,* 3 (3), 10.

Bachoo, P., Brazzelli, M. & Grant, A. (2002). *Surgery for faecal incontinence in adults,* The Cochrane Library, Issue 1, Oxford: Update Software.

Baeten, C. G., Geerdes, B. P. et al (1995). 'Anal dynamic graciloplasty in the treatment of intractable fecal incontinence', *New England Journal of Medicine,* 332 (24), 1600-1605.

Bakke, A., Myhr, K. M. et al (1996). 'Bladder, bowel and sexual dysfunction in patients with multiple sclerosis - a cohort study', *Scandinavian Journal of Urology and Nephrology,* 179, 61-66.

Bytzer, P., Talley, N. J. et al (2001). 'Prevalence of gastrointestinal symptoms associated with diabetes mellitus: a population-based survey of 15,000 adults', *Archives of Internal Medicine,* 161 (16), 1989-1996.

Chaliha, C., Sultan, A. H. et al (2001). 'Anal function: Effect of pregnancy and delivery', *American Journal of Obstetrics and Gynecology,* 185 (2), 427-432.

Chapman, A. (2001). *Systematic review of dynamic graciloplasty for the treatment of faecal incontinence,* ASERNIP-S, Adelaide, South Australia.

Chassagne, P., Landrin, I. et al (1999). 'Fecal incontinence in the institutionalized elderly: Incidence, risk factors, and prognosis', *American Journal of Medicine,* 106 (2), 185-190.

Cheetham, M. J., Malouf, A. J. & Kamm, M. A. (2001). 'Fecal incontinence', *Gastroenterology clinics of North America,* 30 (1), 115-130.

Chia, Y. W., Fowler, C. J. et al (1995). 'Prevalence of bowel dysfunction in patients with multiple sclerosis and bladder dysfunction', *Journal of Neurology,* 242 (2), 105-108.

Christiansen, J. (1992a). 'Advances in the surgical management of anal incontinence', *Bailliere's Clinical Gastroenterology,* 6 (1), 43-57.

Christiansen, J. (1992b). 'Advances in the surgical management of anal incontinence', *Memoires. Academie de Chirurgie (France),* 118 (5), 277-282; discussion 282-283.

Christiansen, J. (1998). 'Modern surgical treatment of anal incontinence', *Annals of Medicine,* 30 (3), 273-277.

Christiansen, J. (2000). 'The artificial anal sphincter', *Canadian Journal of Gastroenterology,* 14 Suppl D, 152D-154D.

Christiansen, J. & Lorentzen, M. (1987). 'Implantation of artificial sphincter for anal incontinence', *The Lancet,* 2 (8553), 244-245.

Christiansen, J. & Lorentzen, M. (1989). 'Implantation of artificial sphincter for anal incontinence. Report of five cases', *Diseases of the Colon and Rectum,* 32 (5), 432-436.

Christiansen, J., Rasmussen, O. O. & Lindorff-Larsen, K. (1999). 'Long-term results of artificial anal sphincter implantation for severe anal incontinence', *Annals of Surgery,* 230 (1), 45-48.

Christiansen, J. & Sparso, B. (1992). 'Treatment of anal incontinence by an implantable prosthetic anal sphincter', *Annals of Surgery,* 215 (4), 383-386.

Commonwealth Department of Health and Aged Care *Medicare Benefits Schedule* [Internet]. Available from: http://www.health.gov.au/pubs/mbs/mbs6/cat3gro6.htm#Items-32203 [30 September 2002].

Crawford, L. A., Quint, E. H. et al. (1993). 'Incontinence following rupture of the anal sphincter during delivery', *Obstetrics and Gynecology,* 82 (4 Pt 1), 527-531.

Devesa, J. M., Rey, A. et al (2002). 'Artificial anal sphincter: complications and functional results of a large personal series', *Diseases of the Colon and Rectum,* 45 (9), 1154-1163.

Dodi, G., Melega, E. et al. (2000). 'Artificial bowel sphincter (ABS) for severe faecal incontinence: A clinical and manometric study', *Colorectal Disease,* 2 (4), 207-211.

Donnelly, V., Fynes, M. et al (1998). 'Obstetric events leading to anal sphincter damage', *Obstetrics and Gynecology,* 92 (6), 955-961.

Downs, S. H. & Black, N. (1998). 'The feasibility of creating a checklist for the assessment of the methodological quality both of randomised and non-randomised studies of health care interventions', *Journal of Epidemiology and Community Health,* 52 (6), 377-384.

Drossman, D. A., Li, Z. M. et al (1993). 'United-States householder survey of functional gastrointestinal disorders - prevalence, sociodemography, and health impact', *Digestive Diseases and Sciences,* 38 (9), 1569-1580.

Eason, E., Labrecque, M. et al (2002). 'Anal incontinence after childbirth', *Canadian Medical Association Journal,* 166 (3), 326-330.

Edwards, N. I. & Jones, D. (2001). 'The prevalence of faecal incontinence in older people living at home', *Age and Ageing,* 30 (6), 503-507.

Faltin, D. L., Sangalli, M. R. et al (2001a). 'Prevalence of anal incontinence and other anorectal symptoms in women', *International Urogynecology Journal and Pelvic Floor Dysfunction,* 12 (2), 117-121.

Faltin, D. L., Sangalli, M. R. et al (2001b). 'Does a second delivery increase the risk of anal incontinence?', *British Journal of Obstetrics and Gynaecology,* 108 (7), 684-688.

Fornell, E. K., Berg, G. et al (1996). 'Clinical consequences of anal sphincter rupture during vaginal delivery', *Journal of the American College of Surgeons,* 183 (6), 553-558.

Gelet, A., Meunier, P. et al (1997). 'Treatment of dual urinary and fecal incontinence by implantation of two AMS 800 artificial sphincters. Case report', *European Urology,* 31 (1), 115-117; discussion 117-118.

Gordon, D., Groutz, A. et al (1999). 'Anal incontinence: Prevalence among female patients attending a urogynecologic clinic', *Neurourology and Urodynamics,* 18 (3), 199-204.

Groutz, A., Fait, G. et al (1999). 'Incidence and obstetric risk factors of postpartum anal incontinence', *Scandinavian Journal of Gastroenterology,* 34 (3), 315-318.

Hajivassiliou, C. A. & Finlay, I. G. (1997). 'Artificial anal sphincter', *Diseases of the Colon and Rectum,* 40 (10), 1261.

Hajivassiliou, C. A. & Finlay, I. G. (1998). 'Effect of a novel prosthetic anal neosphincter on human colonic blood flow', *British Journal of Surgery,* 85 (12), 1703-1707.

Health Insurance Commission *Medicare Benefits Schedule (MBS) item statistics reports* [Internet]. Available from: http://www.hic.gov.au/statistics/dyn_mbs/forms/mbs_tab4.shtml [30 September 2002].

Heiblum, M. & Cordoba, A. (1978). 'An artificial sphincter: a preliminary report', *Diseases of the Colon and Rectum,* 21 (8), 562-566.

Hojberg, K. E., Salvig, J. D. et al (2000). 'Flatus and faecal incontinence: Prevalence and risk factors at 16 weeks of gestation', *British Journal of Obstetrics and Gynaecology,* 107 (9), 1097-1103.

Hoogerwerf, W. A. & Pasricha, P. J. (1999). 'Taking control of fecal incontinence: early results of an artificial sphincter device', *Gastroenterology,* 116 (4), 1005-1006.

Johanson, J. F., Irizarry, F. & Doughty, A. (1997). 'Risk factors for fecal incontinence in a nursing home population', *Journal of Clinical Gastroenterology,* 24 (3), 156-160.

Johanson, J. F. & Lafferty, J. (1996). 'Epidemiology of fecal incontinence: The silent affliction', *The American Journal of Gastroenterology,* 91 (1), 33-36.

Jorge, J. M. & Wexner, S. D. (1993). 'Etiology and management of fecal incontinence', *Diseases of the Colon and Rectum,* 36 (1), 77-97.

Kalantar, J. S., Howell, S. & Talley, N. J. (2002). 'Prevalence of faecal incontinence and associated risk factors: an underdiagnosed problem in the Australian community?', *Medical Journal of Australia,* 176 (2), 54-57.

Kamm, M. A. (1998). 'Faecal incontinence', *British Medical Journal,* 316 (7130), 528-532.

Kamm, M. A. (2002). 'Faecal incontinence: common and treatable', *Medical Journal of Australia,* 176 (2), 47-48.

Khullar, V., Damiano, R. et al (1998). 'Prevalence of faecal incontinence among women with urinary incontinence', *British Journal of Obstetrics and Gynaecology,* 105 (11), 1211-1213.

Lam, T. C. F., Kennedy, M. L. et al (1999). 'Prevalence of faecal incontinence: obstetric and constipation-related risk factors; a population-based study', *Colorectal Disease,* 1, 197-203.

Lee, S. L., DuBois, J. J. et al (2002). 'Surgical management of chronic unremitting constipation and fecal incontinence associated with megarectum: A preliminary report', *Journal of Pediatric Surgery,* 37 (1), 76-79.

Lehur, P. A. (1998). 'Artificial anal sphincter', *Diseases of the Colon and Rectum,* 41 (9), 1201.

Lehur, P. A. (1999a). 'The anal artificial sphincter in severe anal incontinence', *International Journal of Surgical Investigation,* 1 (3), 268-269.

Lehur, P. A. (1999b). 'Effect of a novel prosthetic anal neosphincter on human colonic blood flow', *British Journal of Surgery,* 86 (8), 1096-1097; discussion 1097-1098.

Lehur, P. A., Glemain, P. et al (1998). 'Outcome of patients with an implanted artificial anal sphincter for severe faecal incontinence - A single institution report', *International Journal of Colorectal Disease,* 13 (2), 88-92.

Lehur, P. A., Michot, F. et al (1996). 'Results of artificial sphincter in severe anal incontinence. Report of 14 consecutive implantations', *Diseases of the Colon and Rectum,* 39 (12), 1352-1355.

Lehur, P. A., Roig, J. V. & Duinslaeger, M. (2000). 'Artificial anal sphincter: Prospective clinical and manometric evaluation', *Diseases of the Colon and Rectum,* 43 (8), 1100-1106.

Lehur, P. A., Zerbib, F. et al (2002). 'Comparison of quality of life and anorectal function after artificial sphincter implantation', *Diseases of the Colon and Rectum,* 45 (4), 508-513.

Leroi, A. M., Weber, J. et al (1999). 'Prevalence of anal incontinence in 409 patients investigated for stress urinary incontinence', *Neurourology and Urodynamics,* 18 (6), 579-590.

Lynch, A. C., Dobbs, B. R. et al (2001). 'The prevalence of faecal incontinence and constipation in a general New Zealand population; a postal survey', *New Zealand Medical Journal,* 114 (1142), 474-477.

MacArthur, C., Glazener, C. M. A. et al (2001). 'Obstetric practice and faecal incontinence three months after delivery', *British Journal of Obstetrics and Gynaecology,* 108 (7), 678-683.

MacLennan, A. H., Taylor, A. W. et al (2000). 'The prevalence of pelvic floor disorders and their relationship to gender, age, parity and mode of delivery', *British Journal of Obstetrics and Gynaecology,* 107 (12), 1460-1470.

Madoff, R. D., Baeten, C. G. et al (2000). 'Standards for anal sphincter replacement', *Diseases of the Colon and Rectum,* 43 (2), 135-141.

Madoff, R. D., Rosen, H. R. et al (1999). 'Safety and efficacy of dynamic muscle plasty for anal incontinence: lessons from a prospective, multicenter trial', *Gastroenterology,* 116 (3), 549-556.

Madoff, R. D., Williams, J. G. & Caushaj, P. F. (1992). 'Fecal incontinence', *New England Journal of Medicine,* 326 (15), 1002-1007.

Malouf, A. J., Chambers, M. G. & Kamm, M. A. (2001). 'Clinical and economic evaluation of surgical treatments for faecal incontinence', *British Journal of Surgery,* 88 (8), 1029-1036.

Malouf, A. J., Vaizey, C. J. et al (2000). 'Reassessing artificial bowel sphincters', *The Lancet,* 355 (9222), 2219-2220.

Mander, B. J. & Williams, N. S. (1996). 'Patient selection is integral to the success of the electrically stimulated gracilis neosphincter', *Diseases of the Colon and Rectum,* 39 (6), 712-713.

Michot, F., Lehur, P. A. & Forestier, F. (1997). 'Artificial anal sphincter', *Seminars in Colon and Rectal Surgery,* 8 (2), 116-120.

MSAC. (1999). *Placement of artificial bowel sphincters in the management of faecal incontinence,* Medical Services Advisory Committee, Canberra.

Nakanishi, N., Tatara, K. et al (1997). 'Urinary and fecal incontinence in a community-residing older population in Japan', *Journal of the American Geriatrics Society,* 45 (2), 215-219.

Narasimhan, K. L. (1993). 'Treatment of anal incontinence by an implantable prosthetic anal sphincter', *Annals of Surgery,* 217 (3), 308.

National Health and Medical Research Council (1999). *A guide to the development, implementation and evaluation of clinical practice guidelines,* (NHMRC) Commonwealth of Australia, Canberra, ACT.

National Health and Medical Research Council (2000). *How to use the evidence: assessment and application of scientific evidence,* (NHMRC) Commonwealth of Australia, Canberra, ACT.

Nelson, R., Furner, S. & Jesudason, V. (1998). 'Fecal incontinence in Wisconsin nursing homes - prevalence and associations', *Diseases of the Colon and Rectum,* 41 (10), 1226-1229.

Nelson, R., Norton, N. et al (1995). 'Community-based prevalence of anal incontinence', *Journal of the American Medical Association,* 274 (7), 559-561.

Niriella, D. A. & Deen, K. I. (2000). 'Neosphincters in the management of faecal incontinence', *British Journal of Surgery,* 87 (12), 1617-1628.

O'Brien, P. E. & Skinner, S. (2000). 'Restoring control: the Acticon Neosphincter artificial bowel sphincter in the treatment of anal incontinence', *Diseases of the Colon and Rectum,* 43 (9), 1213-1216.

Ortiz, H., Armendariz, P. et al (2002). 'Complications and functional outcome following artificial anal sphincter implantation', *British Journal of Surgery,* 89 (7), 877-881.

Peet, S. M., Castleden, C. M. & McGrother, C. W. (1995). 'Prevalence of urinary and faecal incontinence in hospitals and residential and nursing homes for older people', *British Medical Journal,* 311 (7012), 1063-1064.

Perry, S., Shaw, T. et al (2002). 'Prevalence of faecal incontinence in adults aged 40 years or more living in the community', *Gut,* 50 (4), 480-484.

Prophet, S. (2002). 'ICD-9 Committee explores new technology, drug codes', *Journal of American Health Information Management Association,* 73 (4), 64-69.

Rizk, D. E. E., Hassan, M. Y. et al (2001). 'The prevalence and determinants of health care-seeking behavior for fecal incontinence in multiparous United Arab Emirates females', *Diseases of the Colon and Rectum,* 44 (12), 1850-1856.

Roberts, R. O., Jacobsen, S. J. et al (1999). 'Prevalence of combined fecal and urinary incontinence: A community-based study', *Journal of the American Geriatrics Society,* 47 (7), 837-841.

Rockwood, T. H., Church, J. M. et al (2000). 'Fecal Incontinence Quality of Life Scale: quality of life instrument for patients with fecal incontinence', *Diseases of the Colon and Rectum,* 43 (1), 9-16; discussion 16-17.

Rotholtz, N. A. & Wexner, S. D. (2001). 'Surgical treatment of constipation and fecal incontinence', *Gastroenterology Clinics of North America,* 30 (1), 131-166.

Ruppert, P. & Staimmer, D. (1998). 'Fecal incontinence - new surgical treatments. ABS-artificial bowel sphincter', *Krankenpflege Journal,* 36 (10), 376-378.

Savoye, G., Leroi, A. M. et al (2000). 'Manometric assessment of an artificial bowel sphincter', *British Journal of Surgery,* 87 (5), 586-589.

Scott, F. B., Bradley, W. E. & Timm, G. W. (1973). 'Treatment of urinary incontinence by implantable prosthetic sphincter', *Urology,* 1 (3), 252-259.

Stata Corporation. (2001). *Intercooled Stata 7.0 for Windows 98/95/NT* [computer programme], Stata Corporation, College City, Texas.

Sultan, A. H., Kamm, M. A. et al (1993). 'Anal-sphincter disruption during vaginal delivery', *New England Journal of Medicine,* 329 (26), 1905-1911.

Talley, N. J., O'Keefe, E. A. et al (1992). 'Prevalence of gastrointestinal symptoms in the elderly: a population-based study', *Gastroenterology,* 102 (3), 895-901.

Vaizey, C. J., Kamm, M. A. et al (1998a). 'Clinical, physiological, and radiological study of a new purpose-designed artificial bowel sphincter', *The Lancet,* 352 (9122), 105.

Vaizey, C. J., Kamm, M. A. & Nicholls, R. J. (1998b). 'Recent advances in the surgical treatment of faecal incontinence', *British Journal of Surgery,* 85 (5), 596-603.

Varma, A., Gunn, J. et al (1999). 'Obstetric anal sphincter injury: prospective evaluation of incidence', *Diseases of the Colon and Rectum,* 42 (12), 1537-1543.

Ware, J., Snow, K. et al (1993). *SF-36 health survey. Manual and interpretation guide,* The Health Institute, New England Medical Centre, Boston.

Wong, W. D., Congliosi, S. M. et al (2002). 'The safety and efficacy of the artificial bowel sphincter for fecal incontinence: results from a multicenter cohort study', *Diseases of the Colon and Rectum,* 45 (9), 1139-1153.

Wong, W. D., Jensen, L. L. et al (1996). 'Artificial anal sphincter', *Diseases of the Colon and Rectum,* 39 (12), 1345-1351.

Young, J., Hyde, C. et al (1999). *Lung volume reduction surgery (LVRS) for chronic obstructive pulmonary disease (COPD) with underlying severe emphysema,* West Midlands Development and Evaluation Committee, Birmingham.

Zetterstrom, J. P., Lopez, A. et al (1999). 'Anal incontinence after vaginal delivery: A prospective study in primiparous women', *British Journal of Obstetrics and Gynaecology,* 106 (4), 324-330.