Placement of Artificial Bowel Sphincters in the Management of Faecal Incontinence

December 1999

MSAC application 1023

Final assessment report

ISBN 0 642 41575 7

First printed December 1999

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

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

This report was prepared by the Medicare Services Advisory Committee with the assistance of Dr Elmer Villanueva and Professor Christopher Silagy from the Australasian Cochrane Centre. The report was endorsed by the Commonwealth Minister for Health and Aged Care on 30 November 1999.

Publication approval number: 2665

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

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The procedure

The use of artificial bowel sphincters in the management of faecal incontinence involves the surgical implantation of a fluid-filled silicone elastomeric device around the anal canal to simulate the normal opening and closing. This action is manually controlled by the patient, allowing for the peristaltic removal of stool.

Medicare Services Advisory Committee — role and approach

The Medicare 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. MSAC advises the Minister for Health and Aged Care on the evidence relating to the safety, effectiveness, and cost-effectiveness of new 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. The medical literature available on the technology is searched and the evidence assessed and classified according to the National Health and Medical Research Council (NHMRC) four-point hierarchy of evidence.[1] A supporting committee with expertise in this area then evaluates the evidence and provides advice to MSAC.

Assessment of placement of artificial bowel sphincters in the management of faecal incontinence

The only clinical studies currently available on the use of artificial bowel sphincters in the management of faecal incontinence are case reports or case-series studies on selected population groups (level IV evidence). None of these studies has included a control or comparison group.

Burden of disease

Injuries caused by surgery or childbirth are the most common cause of faecal incontinence but there are no reliable estimates of the burden of morbidity. The prevalence of faecal incontinence in the population is difficult to measure but it has been estimated to be 2–7% overall and higher for some groups, including those over 50 years of age and those requiring institutionalised care.

Safety

There are insufficient data to assess the safety profile of the device. There have been limited short-term studies, but significant methodological flaws limit the inferences that can be drawn.

Effectiveness

The effectiveness of artificial bowel sphincters in faecal incontinence has not been demonstrated due to the lack of rigorous studies.

Cost-effectiveness

An assessment of the cost-effectiveness of the technology is not possible given uncertainty about the device's effectiveness and safety.

Recommendation

Since there is currently insufficient evidence pertaining to placement of artificial bowel sphincters in the management of faecal incontinence, MSAC recommended that public funding should not be supported at this time for this procedure.

Introduction

The Medicare Services Advisory Committee (MSAC) has assessed placement of artificial bowel sphincters in the management of faecal incontinence. MSAC evaluates new 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. MSAC adopts an evidence-based approach to its assessments, based on reviews of the scientific literature and other information sources, including clinical expertise.

MSAC's terms of reference and membership are shown in Appendix A. 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 affairs and health administration.

This report summarises the current evidence relating to the safety and effectiveness of placement of artificial bowel sphincters in the treatment of faecal incontinence.

Background

Faecal incontinence

Faecal continence is defined as 'the voluntary deferment of the passage of enteric contents to a socially acceptable time and place'.[2] The inadequacy or complete loss of this voluntary control — commonly known as anal or faecal incontinence — is symptomatic of underlying pathology and not, in itself, a diagnosis. Faecal incontinence involves some disturbance in the complex interplay of mental function, stool volume, consistency and transit through the colon, rectal distensibility, anorectal perception, excretion and retention, or any combination of these factors.[3, 4] A distinct definition of the condition has not currently been agreed upon, making measurement of its impact and severity difficult.[5]

The causes of faecal incontinence are varied (see Table 1). Congenital anomalies of the anorectal area may range from an imperforate anus to total absence of the rectum.[7] Surgery and childbirth are leading causes of trauma to the anal sphincter in mid-life,[8] while incontinence due to outlet obstruction is the leading cause of incontinence in the elderly.[6]

Table 1 Causes of faecal incontinence

Pelvic floor	Type of incontinence	Cause
Normal	Diarrhoeal states	Gastrointestinal diseases
	Overflow	Impaction
		Encopresis
		Rectal neoplasms
	Neurologic conditions	Congenital anomalies (eg myelomeningocele) Multiple sclerosis Dementia, strokes, tabes dorsalis Neuropathy (eg diabetes) Neoplasms of the brain, spinal cord, cauda equina
Abnormal	Congenital anorectal malformation	Congenital
	Trauma	Accidental injury (eg impalement, pelvic fracture) Anorectal surgery Obstetrical injury
	Ageing	Muscle/nervous degeneration
	Pelvic floor denervation (idiopathic neurogenic incontinence)	Vaginal delivery Chronic straining at stool Rectal prolapse Descending perineum syndrome

Source: Madoff et al[4]

The condition is associated with a broad range of symptoms. Some patients with faecal incontinence may be able to sense the passage of faeces but have only limited ability to control it. This group includes people with motor deficits from sphincter or pelvic floor injuries. Other people may be unaware that faeces has been passed.[3] This includes people with sensory impairment, such as those with neuropathic faecal incontinence or rectal

prolapse. Some people complain of incontinence only to flatus, liquids or solids; others report infrequent, intermittent episodes rather than continuous affliction.

People with faecal incontinence may be personally and socially incapacitated. Even episodic bouts of incontinence have severe consequences on self-confidence, personal image, and social integration.[9,10] Many patients have reported problems in social role functioning and sexual performance that are directly attributable to their condition.[10–13]

There have been few studies on the economic impact of faecal incontinence. They suggest that the disorder can be very costly.[14,15] Data from the 1996 United States Health Care Financing Administration inpatient database indicated that the average cost per patient was US$17,166, with evaluation and follow-up charges of US$65,412 and treatment charges of US$559,341.[16]

No studies were found that describe the economic burden associated with the condition from an Australian perspective.

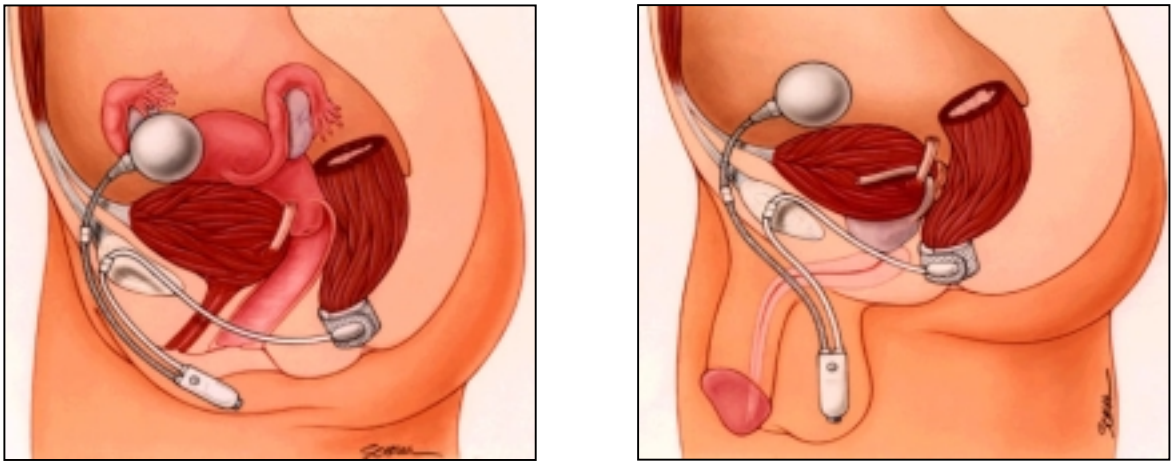
The procedure

Artificial sphincters have been used to treat urinary incontinence since 1973.[17,18] In 1987, Christiansen and Lorentzen[19] applied a version of this device (called the AMS 800® Urinary Sphincter, or AUS®) to a patient with faecal incontinence. The AUS was designed by American Medical Systems (Minnesota, USA) to function as a totally implantable system. It consists of an occlusive cuff, control pump, and pressure-regulating balloon. The control pump contains the valves used in the transfer of fluid to and from the cuff. The device was designed with a cuff width of 2 cm, cuff length of 4–11 cm, and cuff pressure of 41–50 cm H_2O when deflated and 81–90 cm H_2O when inflated.

In 1996, AMS introduced a new sphincter design specifically for implantation around the bowel (Figure 1). This artificial bowel sphincter (ABS) also consisted of a cuff, control pump and regulating balloon, but had several major differences[20] including:

- three choices of cuff width: 2 cm, 2.9 cm, and 3.4 cm;
- cuff lengths ranging from 7 to 12 cm;
- higher cuff pressures: 51–60 cm H_2O (deflated) and 111–120 cm H_2O (inflated);
- a larger pump to allow more rapid rate of fluid emptying; and
- the addition of a septum for fine adjustment of fluid content by percutaneous aspiration or injection.

Figure 1 Placement of the AMS artificial bowel sphincter. The control pump assembly is situated in the labia majora in females (left) or in the scrotum in males (right) (American Medical Systems[21]).



Acknowledgements: ActiconTM Neosphincter, Courtesy of American Medical Systems, Inc. Minnetonka, Minnesota, Illustrations by Michael Schenk

The implantation procedure involves the surgical insertion of a cuff in a tunnel around the anal canal, tubing between the cuff and an abdominal incision, a balloon behind the rectus abdominus, and a pump in the labia majora or scrotum. The cuff is pressurised and the balloon filled with fluid. The pump, tubing and cuff are connected using colour-coded tubing.[20, 22]

The implantation procedure takes approximately 1.5–2 hours and the patient is confined to hospital for 4–5 days after the procedure. Measures to ensure healing free of infection include the prescription of perioperative antibiotics, attention to aseptic technique, and application of antiseptic paste to the perineal wound postoperatively.

The cuff is activated 6 weeks after implantation. Once activated it mimics physiological resting anal pressure by producing a sustained low-pressure anal occlusion that is applied uniformly around the upper canal. Anal pressures measured postoperatively by anal manometry reproduce the resting pressure of the anal canal. The patient can then control defecation manually by compressing the pump located in the labium or the scrotal sac 5–10 times. This displaces the pressurised fluid from the cuff to the pressure balloon, allowing faeces to pass through the anal canal. Re-closing occurs automatically within 3–8 minutes when initial volume is re-established in the pressure balloon, restoring the balance of pressure in the entire device.[23]

Intended purpose

Artificial bowel sphincters are indicated for patients with severe faecal incontinence that seriously disrupts normal functioning and lifestyle and is inadequately controlled by more conservative measures, including bowel control or physiotherapy, and that is not amenable to direct repair of the anal sphincter mechanism.

Other indications include:

- hereditary malformations including spina bifida and imperforate anus;

- neurological diseases including diabetic neuropathy, cauda equina neuroma, and myasthenia gravis;
- destruction of the sphincter above its hemicircumference (eg due to obstetric trauma or after colorectal or proctological surgery); and
- neuropathy in the absence of sphincter defects.

Contraindications to the procedure include:[23, 24]

- previous patient history of adverse reaction to radiopaque solution used as a filling medium in the prosthesis;
- tissue fibrosis in the area of the implant precluding implantation of the occlusive cuff at the anal canal;
- absence of the rectovaginal wall secondary to extensive anterior perineal destruction or a congenital malformation (eg anal atresia and vulvovaginal anus);
- radiation-induced lesions of the perineum and bowel; and
- absence of a rectal reservoir.

Burden of disease

It is difficult to estimate morbidity due to faecal incontinence, because of the social stigma attached to the problem. Patients are often unwilling to admit having faecal incontinence, while medical practitioners are often reluctant to inquire about it.[4] In a series of subjects with diarrhoea, fewer than half of patients admitting to incontinence volunteered the information spontaneously.[12] In another study, up to 30% of patients with gastrointestinal disorders had symptoms of incontinence but only up to 5% of these patients, regardless of the underlying mechanism, had these symptoms noted in their medical records.[25]

Considering these difficulties, it is not surprising that prevalence and incidence are thought to be underestimated, especially in middle-aged women, in whom injury of the pelvic floor after childbirth is common.[26]

Prevalence

Population-based studies of faecal incontinence estimate the prevalence of the condition to be between 2% and 7% (Table 2).

The prevalence of incontinence is much higher in older people and in selected populations, sometimes approaching 5–15 times general population estimates. There is no standard definition for the condition so the term may be interpreted in different ways.

Lam et al[43] performed a population-based study using a random sample of the electoral roll of Southern Sydney in 1998. They used a strict definition of faecal incontinence — affirmation of at least two of three questions focusing on stool leakage, pad use for faecal soiling, and incontinence to flatus occurring more than 25% of the time. The prevalence

of faecal incontinence in this population was 15%, and the condition was more prevalent in males than females (20% versus 11%).

Table 2 Prevalence of faecal incontinence in general, older adult, and special populations

Author	Location of study	Population and setting	Prevalence (per 100)
General population:			
Nelson et al 1995[27]	USA	Community survey	2.2
Giebel et al 1998[28]	Germany	Adult volunteers	4.8
Roig Vila et al 1993[29]	Spain	Working adults	6.8
Older adults:			
Peet et al 1995[30]	UK	Adults over 65 from institutions	3.1
Campbell et al 1985[31]	USA	Adults over 65 (community and institutions)	3.1
Nakanishi et al 1997[32]	Japan	Adults over 65 (community)	9.8
Tobin and Brocklehurst 1986[33]	USA	Residential homes population	10.3
Lopes et al 1997[34]	Brazil	Geriatric ambulatory service	10.9
Denis et al 1992[35]	France	Poll of adults over 45	11
Roberts et al 1999[36]	USA	Adults over 50 (community)	11.1[a] 15.2[b]
Kok et al 1992[37]	The Netherlands	Adults over 85 (community)	16.9
Special populations:			
Johanson and Lafferty 1996[11]	USA	Patients seen by family practitioner or gastroenterologist	18.4
Amaral et al 1997[38]	Brazil	Diabetic outpatients	18.6
Gordon et al 1999[39]	Israel	Urogynaecologic outpatient clinic	30
Nakayama et al 1997[40]	Denmark	Acute stroke patients	34
Borrie and Davidson 1992[15]	UK	Long-term care hospital	46
Hinds et al 1990[41]	USA	Multiple sclerosis patients	51
Topinkova et al 1997[42]	Czech Republic	Patients in geriatric facilities	54.4

a Males.
b Females.

Incidence

Studies identifying the development of new cases of faecal incontinence are difficult to locate (Table 3). In a study involving institutionalised adults in France, 234 of 1186 subjects developed some degree of faecal incontinence after 10 months of follow-up.[44] The follow-up of special populations may provide better estimates as these groups are identified by some special characteristics (eg post-prostatectomy patients, etc), but this also makes generalisation of the estimates difficult.

Table 3 Incidence of faecal incontinence

Author	Location of study	Population and setting	Incidence proportion (per 100)
Chassagne et al 1999[44]	France	Institutionalised adults over 60	20
Bishoff et al 1998[45]	USA	Post-prostatectomy patients	18[a]
			5[b]
Javid et al 1998[46]	USA	Girls with low imperforate anuses	47

a Following radical perineal prostatectomy.
b Following retropubic prostatectomy.

Existing procedures

There are three broad treatment categories for faecal incontinence: medical therapy, physiotherapy including biofeedback and strengthening exercises, and surgery (Table 4). In faecal incontinence secondary to an underlying gastrointestinal condition, it is generally accepted that treatment of the precipitating cause must take precedence.[3,4,47]

Table 4 Therapy for faecal incontinence[a]

Medical	Physiotherapy	Surgical
Dietary	Strengthening exercises	Sphincter repair
Pharmacologic	Biofeedback	Encirclement procedures
Bowel management		Synthetic materials
		Muscle transfer
		Artificial sphincters
		Abdominal stomata

a Modified from Jorge and Wexner[47] and Schmitt and Wexner.[48]

Conservative treatment for mild degrees of the disorder involves the use of bulking and pharmacologic agents that provide better control of the stool.[49,50] Strengthening exercises involving a daily routine of repeated contractions of the perineal muscles have been recommended,[51] but there has been no objective validation of this technique.[47] In biofeedback, voluntary sphincter activity that strengthens sphincteric tone is encouraged through the use of a sensing device that measures pressure changes or electromyographic responses.[52]

Surgical procedures are generally reserved for people with defined defects of the anal sphincter or who have not benefited from more conservative measures. Anal sphincter repair, including sphincter reconstruction, is best performed when visible separation of the muscle is present.[3,4,22,47] If failure occurs after repeated attempts to repair the muscle or if no structural defects are evident, procedures involving the encirclement of the anus using transferred (syngeneic) tissue or synthetic material are considered. If substantial incontinence persists after medical, physiotherapeutic or surgical procedures, an abdominal stoma may be required.

This report examines the effectiveness of artificial sphincters compared to stimulated syngeneic muscle transfers in the control of intractable faecal incontinence that has not responded to treatment using more conservative approaches.

Comparator

In this assessment, the use of artificial bowel sphincters has been compared with dynamic graciloplasty. This procedure involves mobilisation of the gracilis muscle from the medial aspect of the thigh by severing its distal tibial attachment while retaining its nerve supply and main blood supply. The muscle is looped around the anal canal and its distal end is fixed to the bony pelvis. A low-frequency neurostimulator is implanted in the abdominal wall and continuous stimulation converts the muscle from its native fast-twitch, fatigable state to one that is slow-twitch and less fatigable. Tonic contraction of the muscle occludes the anal canal, providing some degree of continence. Relaxation of the gracilis is achieved by passing a magnet over the stimulator to switch it off. A second pass re-activates the stimulator, and a return to continence is achieved. First performed by Baeten and colleagues in 1986,[53] the procedure has been generally accepted as a treatment option for severe faecal incontinence.[22] However, there have been no controlled trials to confirm the effectiveness of the procedure.

Marketing status of the device

The Therapeutic Goods Administration (TGA) listed the American Medical Systems artificial bowel sphincter (ABS) under AUST L Number 12950 on August 13, 1996.

Current reimbursement arrangement

There is currently no specific Medicare Benefits Schedule (MBS) item number for the ABS. The comparator, dynamic graciloplasty, is currently covered in the MBS under item numbers 32200, 32203, 32206, 32209, and 32210.

Approach to assessment

Review of literature

The medical literature was searched to identify relevant studies and reviews, following established procedures outlined in the Cochrane Collaboration Handbook.[54] A total of seven databases were searched (Table 5). Anticipating the paucity of a high level of evidence, a search strategy that was more sensitive than specific was used.[55] This included Internet sources and health technology assessment sites.

Table 5 Databases and search terms used in the literature search

Database	Edition	Search terms[a]
Cochrane Library	Issue 3 1999; searched on 27 Aug 1999	Fecal incontinence, anal incontinence, artificial bowel sphincter, artificial anal sphincter, anus, prostheses and implants
Medline; Biological Abstracts; CINAHL	1966 to Sept Week 5 1999; searched on 27 Aug 1999	Artificial bowel sphincter, artificial anal sphincter, fecal incontinence, anal incontinence, anus (surgery), prostheses and implants
Best Evidence	1991–1999; searched on 27 Aug 1999	Fecal incontinence, anal incontinence, sphincter
HealthSTAR; PubMed	Sept Week 5 1999; searched on 27 Aug 1999	Artificial bowel sphincter, artificial anal sphincter, fecal incontinence, anal incontinence, anus (surgery), prostheses and implants

a UK English spelling variations were also included (eg faecal). The precise search terms used are available upon request.

In addition to database and Internet searches, reference lists of retrieved studies were searched, experts in the field were invited to provide additional information about the topic and the manufacturer of the device was contacted and requested to provide product information.

As a result of this search strategy, 46 studies were retrieved.

Inclusion and exclusion criteria

The following inclusion/exclusion criteria was applied to the collected studies:

- description of a primary study involving the use of the American Medical Systems ABS or the AUS (AMS 800) in the management of faecal incontinence in humans;
- data was not included in another published study; and
- the publication was in English.

Seven studies[20,23,56–60] satisfied the above criteria; 39 studies were excluded for reasons given in Table 6. Eighteen studies were excluded because they did not report primary data. These consisted of narrative reviews, letters to the editor and editorials. Eleven non-English studies were not critically appraised as expert advice from the supporting

committee suggested that the evidence reported in studies published in languages other than English were unlikely to be different from English language studies. In five instances, data from a small pool of patients were reported, duplicating data previously presented in other articles or reports. The excluded studies are listed in Appendix C.

Table 6 Reasons for exclusion of studies identified in the search

Reason for exclusion	Number of studies
Publication not a primary study (ie reviews, letters to the editor, editorials, etc)	18
Publication in a language other than English	11
Data included in another study	5
Prosthesis used was not AMS ABS or AUS AMS 800	3
Animal study	2

The evidence presented in seven studies satisfying the entry criteria was assessed and classified according to the NHMRC-revised hierarchy of evidence shown in Table 7.

Table 7 Designation of levels of evidence

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 pseudo-randomised controlled trials (alternate allocation or some other method).
III-2	Evidence obtained from comparative studies with concurrent controls and allocation not randomised (cohort studies), case-control studies or interrupted time series with control group.
III-3	Evidence obtained from comparative studies with historical control, two and 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 and post-test.

Source: NHMRC[1]

Expert advice

A supporting committee including members with expertise in relation to the management of faecal incontinence was convened to assess the evidence on this procedure. In selecting members for supporting committees, MSAC's practice is to approach medical colleges, specialist societies and associations and consumer bodies for nominees. Membership of the supporting committee is shown in Appendix B.

Results of assessment

The ideal study design for assessing the clinical effectiveness of a therapeutic procedure is a randomised controlled trial (RCT). However, the literature search did not retrieve any RCTs on the use of artificial bowel sphincters. The seven studies identified for inclusion in this assessment (see Table 10) were all descriptive case series and none provided comparisons with a control or placebo group. Hence these studies were of low methodological quality (level IV evidence,[1]). None of the studies considered direct comparisons between ABS/AUS and dynamic graciloplasty.

Is it safe?

The sample sizes of the included studies ranged from 1 to 17 patients, with a total of 60 patients in all the included studies (Table 8). Adverse events associated with the procedure are shown in Table 8. Five of the studies[23, 56–59] (total *n*=41) focused on the follow-up of patients implanted with the AUS while one[20] (*n*=6) looked into the implantation of the ABS. The study by Lehur and colleagues[60] examined the experience of 13 patients, four of whom received the ABS, with the remainder receiving the AUS.

Surgical site infections were common and, although they were controlled by the use of appropriate antibiotics, some cases were serious enough to warrant removal of the device. Erosion of the adjacent skin occurred in four instances. There were no cases of the device eroding through the sphincter musculature and into the anal canal.

Table 8 Immediate post-operative and secondary adverse events

Study	Sample size	Number of episodes[a]			
		Device failure	Surgical site infection	Ulceration or erosion	Faecal impaction
AUS					
Weston et al 1991[56]	1	0	0	0	1
Wong et al 1996[59]	12	2	3	0	0
Gelet et al 1997[58]	1	1	0	0	0
Michot 1998[23]	10	0	2	2	0
Christiansen et al 1999[57]	17	3	3	0	1
ABS					
Lehur et al 1998[60 a]	13	2	1	0	0
Vaizey et al 1998[20 b]	6	0	2	1	0
Totals	60	8	11	3	2

a Several events may occur in individual patients.
b Includes 7 implanted with the AUS.

Seventeen of the 60 implants (28%) required removal (Table 9). The most common reasons for explantation were infections of the surgical site and mechanical malfunctions, each occurring in six of 17 cases. Immediate or early (≤1 month) removal of the artificial sphincter was performed in eight patients (47%), the majority secondary to infection (four of eight cases).

Table 9 Reasons for removal (explantation) of sphincters

Study	Sample size	Explantations		Reasons for explantation
		Number	Immediate or early[a]	
AUS				
Weston et al 1991[56]	1	1	1	Faecal impaction
Wong et al 1996[59]	12	3	0	Infection (*n*=2); mechanical malfunction (*n*=2); patient preference (*n*=2)
Michot 1998[23]	10	1	1	Infection
Christiansen et al 1999[57]	17	7	3	Infection (*n*=3); mechanical malfunction (*n*=2); severe chronic diarrhoea (*n*=2)
Gelet et al 1997[58]	1	0	0	Not applicable
ABS				
Lehur et al 1998[60b]	13	4	2	Mechanical malfunction (*n*=2); patient preference (*n*=1); severe ulcerative colitis (*n*=1)
Vaizey et al 1998[20a]	6	1	1	Erosion of the adjacent skin
Totals	60	17	8	

a Removal of the device during the immediate post-operative period up until 1 month postimplantation.
b Includes seven implanted with the AUS.

Is it effective?

Subjects undergoing implantation were predominantly female (one study[23] did not provide enough information about patient characteristics). Forty per cent of incontinence was due to a neurological disorder (including idiopathic sphincter weakness). Implantation with the sphincters was undertaken in a number of European cities (Table 10).

The longest follow-up was 10 years, although in some cases follow-up was much shorter (see Table 10). A sufficient length of time is necessary for the entire gamut of outcomes to take place. Shorter follow-up times are often associated with early failures, exacerbating potentially biased patient selection. On the other hand, longer follow-up times are not altogether indicative of high success rates, for the same reasons.

Table 10 Description of collected studies

Study	Location	Sample size	Median age[a]	Number of males	Median follow-up[a]	Causes of incontinence
AUS						
Weston et al 1991[56]	UK	1	13	0	1 m	Sacral agenesis
Wong et al 1996[59]	USA/ Scotland	12	33[c] (15–52)	7	58 m[c] (30–76 m)	Obstetric injury (*n*=4); major trauma (*n*=3); neurologic disorder (n=3); imperforate anus (*n*=2)
Gelet et al 1997[58]	France	1	61	0	2 y	Neurologic disorder
Michot 1998[23]	France	10	?[d]	?	?	Unknown
Christiansen et al 1999[57]	Denmark	17	46 (32–65)	6	7 y (5–10 y)	Neurologic disorder (*n*=10); failure of previous treatment (*n*=6); imperforate anus (*n*=1)
ABS						
Lehur et al 1998[60b]	France	13	40 (22–60)	4	30 m[c]	Trauma (*n*=5); imperforate anus (*n*=4); neurologic disorder (*n*=4)
Vaizey et al 1998[20a]	UK	6	53 (32–58)	0	9 m (4–12 m)	Obstetric damage (*n*=3); idiopathic sphincter weakness (*n*=2); imperforate anus *(n*=1)

a In case reports, numbers refer to actual values. In case series, numbers in parentheses are ranges.
b Includes 7 implanted with the AUS.
c Mean value.
d Unknown.

The degree of faecal control that patients experienced after implantation with the AUS are shown in Table 11. Of the total 60 patients studied, only 36 (60%) had follow-up details. Of these 36 patients, approximately 23 (64%) were continent to solid faeces, 23 (64%) were continent to liquid stool, and 15 (42%) were able to control flatus. Therefore, the proportion of patients able to control faeces, liquid stool, and flatus were approximately 38 per cent (23 of 60), 38 per cent (23 of 60), and 25 per cent (15 of 60). However, this apparent continence to solid faeces may be an overestimate, as there is no data on how many of these patients were incontinent to solid faeces before undergoing implantation and whether an improvement in their condition actually resulted.

Table 11 Functional outcomes of subjects after implantation of the AUS

Study	Sample size	Number of patients with adequate follow-up	Number continent[a]		
			Solid stool	Liquid stool	Flatus
Weston et al 1991[56]	1	1	0	0	0
Wong et al 1996[59]	12	7	7	5	4
Gelet et al 1997[58]	1	1	1	1	0
Michot 1998[23]	10	8	8	7	6
Christiansen et al 1999[57]	17	8	7	8	1
Lehur et al 1998[60b]	13	11	?[c]	2	4
Total	54	36	≈23	23	15

a Continence is defined as ranging from resumption of total continence to 'occasional' bouts of incontinence.
b Includes 7 implanted with the AUS.
c Unknown.

In the two studies of patients implanted with the ABS[20, 60] (n=19) continence was measured using a scale developed by Jorge and Wexner[47] in which a score of zero indicated complete continence and 20 referred to incontinence. The mean scores of the patients with follow-up data from the two studies were 2.8 (range: 0 to 6; n=13)[20] and 4.0 (range: 0 to 10; n=6).[60]

Only three studies[20,23,60] looked at the impact of the procedure on the quality of life of patients (n=29). No single instrument was used to measure quality of life among the three studies. Vaizey and colleagues[20] used a quality-of-life questionnaire called Short-Form 36 (SF-36), while Michot[23] describes the use of a questionnaire covering six specific areas with apparent overlap with the domains examined by the SF-36. The quality-of-life instrument used in the study by Lehur et al[60] was not identified. Overall, there were reports of improvements in the role-emotional, social and physical-functioning domains of the SF-36.[20] The studies did not provide data about specific changes, although they made blanket statements attesting to the general improvement of quality of life in subjects implanted with the devices.[23,60]

It is important to emphasise that these findings reflect the experience of a limited number of centres and deal with a select group of subjects who, for unknown reasons and motivations, were chosen (or volunteered) to undergo surgery for placement of an artificial sphincter. The most serious concern is the lack of any control groups with which to make comparisons. Generally, in case series studies, implicit comparisons of the efficacy of a procedure are implicitly compared to a vague set of conditions assumed to be prevalent during the time the study is conducted. It is not clear whether the assumptions made are justified or applicable to other settings.

Another serious concern is the high likelihood of selection bias. As no attempt was made to develop patient criteria before enrolment into the studies, it is difficult to validate outcomes stringently. It is therefore possible that the results of the procedure are attributable to specific subject characteristics selected (consciously or not) during enrolment. Also, because there were no comparison groups, measurement bias cannot be excluded.

The extent to which these problems affect the validity of the studies is difficult to estimate. Moreover, it is not possible to derive conclusions that are directly generalisable to other population groups.

Given these limitations, no conclusions about the clinical effectiveness of the procedure can be drawn until stronger evidence is available. The supporting committee also noted that evidence in support of the comparator, dynamic graciloplasty, is also lacking.

What are the economic considerations?

Since issues of clinical effectiveness and safety remain unresolved, it is not yet possible to perform an economic evaluation of the sphincters and their role in the management of faecal incontinence.

The MBS currently lists fees for dynamic graciloplasty under items 32203–32210. If a two-step approach is taken, graciloplasty costs $488.50 and insertion of the neurostimulator and its electrodes costs $441.30. The two procedures may be performed together, costing $709.20.[61]

Commonwealth Department of Health and Aged Care rebates (for devices on the 1999 Surgically Implanted Prostheses and Homograft Items List) for the ABS and its comparator, dynamic graciloplasty, are given in Table 12. These rebates are provided outside the MBS process.

Table 12 Costs of the artificial bowel sphincter and dynamic graciloplasty

Artificial bowel sphincter			Dynamic graciloplasty		
Item	**Department of Health rebate number[a]**	**Cost**	**Item**	**Department of Health rebate number[a]**	**Cost**
ABS cuff	K038	$3,000.00	Pulse generator	K130	$6,800.00
ABS pump	K039	5,600.00	Leads	K128	5,400.00
ABS pressure balloon	K040	3,000.00	Control magnet	K131	90.00
ABS accessory package	K041	400.00	Extension (extra)	K066	1,350.00
			Lead (extra)	K065	3,500.00
			Accessories (extra)	K126	5,000.00
Total		$12,000.00	Total	Without extras	$12,290.00
				With extras	$22,140.00

a Minister's Determination in respect of Schedule 5, Benefits Payable in Respect of Surgically Implanted Prostheses and Homograft Items, of the Default Benefit (paragraph (bj) Schedule 1 of the *National Health Act 1953*). Effective 3 February 1999.

Conclusions

Safety

Without evidence from rigorously conducted studies, it is impossible to make firm conclusions about the safety profile of the device. However, a number of adverse events were reported, including removal of the device due to failure or surgical site infection, which occurred in about 30% of cases in the studies assessed.

Effectiveness

The use of the artificial bowel sphincter has shown some positive effects in the management of faecal incontinence and the quality of life of patients undergoing the procedure. However, it is difficult to quantify the degree of this benefit due to serious deficiencies in the design of studies conducted to date. There is no strong evidence to determine whether the advantages of this procedure are significantly greater than those of other treatment alternatives (or no treatment) in individuals receiving the device.

Cost-effectiveness

The cost-effectiveness of the procedure is not possible to assess due to a lack of strong evidence on clinical effectiveness and safety.

Recommendation

Since there is currently insufficient evidence pertaining to placement of artificial bowel sphincters in the management of faecal incontinence, MSAC recommended that public funding should not be supported at this time for this procedure.

— The Minister for Health and Aged Care accepted this recommendation on 30 November 1999 —

Appendix A MSAC terms of reference and membership

The terms of reference of the Medicare Services Advisory Committee are to:

- advise the Minister for Health and Aged Care 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 Aged Care 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 Aged Care on references related either to new and/or existing medical technologies and procedures; and
- undertake health technology assessment work referred by the Australian Health Ministers' Advisory Council (AHMAC), and report its findings to AHMAC.

The membership of the Medicare Services Advisory Committee 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**
Professor David Weedon (Chair)	pathology
Ms Hilda Bastian	consumer health issues
Dr Ross Blair	vascular surgery (New Zealand)
Mr Stephen Blamey	general surgery
Dr Paul Hemming	general practice
Dr Terri Jackson	health economics
Mr Alan Keith	Assistant Secretary of the Diagnostics and Technology Branch of the Commonwealth Department of Health and Aged Care
Professor Brendon Kearney	health administration and planning
Dr Richard King	gastroenterology
Dr Michael Kitchener	nuclear medicine
Professor Peter Phelan	paediatrics
Dr David Robinson	plastic surgery
Associate Professor John Simes	clinical epidemiology and clinical trials
Associate Professor Bryant Stokes	neurological surgery, representing the Australian Health Ministers' Advisory Council

Appendix B Supporting committee

Supporting committee for MSAC application 1023
Artificial bowel sphincter

Associate Professor Bryant Stokes (Chair) MBBS, FRACS Chief Medical Officer Health Department of Western Australia	member of MSAC
Associate Professor Michael Solomon MSc, MBBCh, FRACS, LRCS, LRCP Colorectal Specialist Surgeon Royal Prince Alfred Hospital	nominated by the Royal Australasian College of Surgeons
Professor David Fonda BmedSc, MBBS, FRACP, FACRM Geriatrician and Continent Specialist	nominated by the Australian Society for Geriatric Medicine Association
Dr David Lubowski MBChB, FRACS Colorectal Surgeon St George Hospital	nominated by the Colorectal Surgical Society
Dr David Jarvis MBChB, FRACGP, BA, BLitt General Practitioner	nominated by the Royal Australian College of General Practitioners
Ms Liz Symons RN Clinical Nurse Consultant	consumer representative

Appendix C Excluded studies

Nonprimary studies

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Abbreviations

ABS	artificial bowel sphincter
AMS	American Medical Systems
AUS	artificial urinary sphincter
MBS	Medicare Benefits Schedule
MSAC	Medicare Services Advisory Committee
RCT	randomised controlled trial
TGA	Therapeutic Goods Administration

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