Review Article

Artificial bowel sphincters for severe fecal incontinence

Are they a solution?

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ABSTRACT

يعد مرض سلس البراز من المشاكل الشائعة والمنهكة التي تؤثر على المريض من الناحية الطبية والاجتماعية والاقتصادية. يشمل العلاج غير الجراحي كلاً من: تعديل النمط الغذائي، وتعاطي الأدوية المضادة للإسهال، واستخدام طريقة الأثر الرجعي البيولوجي (Biofeedback) مثل عمل التمارين الدورية لمنطقة الحوض و العضلات السفلية. ويمكن تقسيم المرضى الذين يعانون من سلس البراز الشديد إلى فئتين: الفئة الأولى وتضم المرضى الذين يعانون من خلل تشريحي معروف و محدود في العضلة الشرجية العاصرة وفي مثل هذه الحالات يمكن لعملية إصلاح العضلة الشرجية العاصرة أن تنجح على المدى القصيرة وذلك بنسبة تصل إلى 80%، أما الفئة الثانية فهم المرضى الذين لن يستفيدوا من عملة تعديل العضلة الشرجية العاصرة ، كما لا يُحتم عليهم عمل فغارات معوية جانبية (stomas). وتعد عملية زراعة الصمام الاصطناعي الذي يحل محل العضلة الشرجية العاصرة من العمليات الجراحية المعروفة التي تساعد على إيقاف السلس، واستعادة الحياة الطبيعية والوظيفية وذلك بنسبة نجاح عالية. يحتاج الجراح المتخصص إلى فهم كيفية عمل مثل هذه الصمامات، كما يجب عليه إتقان زراعة مختلف أنواعها وذلك بما يتناسب مع حاجة المريض، وعلى الطبيب أيضاً المتابعة المستمرة لحالة المريض من أجل تقديم خدمة أفضل لمثل هذا النوع من الحالات.

Fecal incontinence is a debilitating and common problem with a profound effect on a patient's well being medically, socially, and economically. Non-operative management of this condition includes dietary modification, antidiarrheal medications, and biofeedback. Patients with severe incontinence can be divided into 2 categories. The first group includes patients with an identifiable and isolated anatomic sphincter defect who can expect 80% short-term surgical success using overlapping sphincteroplasty. The second group is patients who will not benefit from sphincteroplasty; fortunately, they are not obligated to permanent stomas. Artificial bowel sphincter (ABS) implantation is a well-established surgical technique, offers a chance for continence, restoration, and improved quality of life with significant functional success rate. The surgeon needs to understand how they function. They should be proficient in different procedure types and match these with the patient's need. Post-operative long-term follow-up continues to help surgeons better serve this type of patient population.

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Fecal incontinence (FI) is defined as recurrent uncontrolled passage of flatus and/or stool for at least one month in an individual who is at least 4 years of age or above.[1] It can be a distressing and incapacitating disorder that can devastate the life of the affected individual. It is a common problem that affects both genders at any age with variable age related prevalence reaching 1.5% in children to approximately 50% in nursing home residents. Both genders seem to have an equally increasing incidence with aging.[2] A survey carried out in the 1990's of American households found that 7.1% of the general population reported having varying degrees of anal incontinence,[3] 11% was found in a French study on 3914 patients,[4] and approximately 1.5-4.8% was found in the Federal Republic of Germany.[5,6] However, the incidence of FI in Saudi Arabia is unknown. It is not typically a popular topic for discussion because of its highly private nature and negative associations. Likewise, worldwide, it is unknown, and difficult to establish because of the unavailability of a standard scoring scale, differences in data collection, under-reporting of symptoms by patients, and variations in the population sample.[7] When both non-operative medical treatment and conventional surgery are ineffective, the artificial bowel sphincter

(ABS) emerges as a choice for these patients who would not otherwise opt for, or accept end colostomy. This technological advancement has opened up the prospect of effective therapy for severe fecal incontinence both in regards to performance and long-term reliability. Searching various biomedical bibliographic databases including MEDLINE, EMBASE, HEALTHSTAR, THE COCHRANE LIBRARY, SCOPUS, CENTRAL, and other non-indexed citations and without any limitations, articles and recently published abstracts of meetings were selected based on greatest clinical relevance. All were reviewed aiming to provide an overview of the different ABS types, their descriptions, how they function, indications, contraindications, clinical results, and their complications.

Historical background. Fetal incontinence can be successfully managed by medical treatment. It includes a wide range of measures such as antidiarrheals, bulk laxatives, and biofeedback, which may, substantially benefit some patients. However, the long-term results depend mainly on patient compliance. Surgical treatment for incontinence can only benefit selected patients. Patients with an identifiable and isolated anatomic sphincter defect can expect 70-90% short-term surgical success with a simple overlapping sphincteroplasty.[8,9] Unfortunately, this repair does not sustain good function in the long run. A 5-year follow-up in 47 patients who had undergone sphincteroplasty for obstetric-related trauma, revealed a success rate of 57% with no need for further therapy, while 14% required further intervention.[10] In another study, at the 10-year follow-up of 191 patients, 40% had gained some improvement in continence and only 6% gained complete continence.[11] Sphincteroplasty is not an option for patients who suffer from extensive sphincter damage, muscle loss, or pudendal neuropathy. In the 1980s, external stimulators were applied to muscle transpositions (dynamic graciloplasty [DGP]) to create dynamic neosphincters with resting muscle tone, which was pioneered by Baeten et al.[12] Wexner et al[13] reported a 62% success rate and improvements in functional and quality of life variables, which persisted for 2 years. However, DGP was associated with high complication (74%) and re-operative rates (40%).[14] Some of these complications led to stoma creation, or death.[15] This leads to the removal of the stimulator device from the US market,[16] and the procedure has not been performed in the United States since 1999,[17] though it does remain a viable option in other countries.[16,18,19] In the 1990s, both sacral nerve stimulation (SNS) and the artificial anal sphincter emerged as other viable options for patients who had undergone and failed simple surgical repairs, complicated muscle rotation procedures, and others who were not candidates for simple overlapping sphincteroplasty, or those who did not wish to undergo more complicated surgeries. A hundred years ago, SNS was described for use in urologic disorders.[20] However, it was not until 1995 that it was adapted for the treatment of fecal incontinence.[21] The SNS procedure is safe with minimal morbidity,[21-24] most commonly, pain (9-26%) at the site of the implantable pulse generator, the subcutaneous tunnel in which the wires run, or at the electrode sites,[25] and superficial wound infection (3-17%).[20] Although long-term data are not yet mature, the medium-term results are promising. In the last review,[26] published by the International Consultation on Fecal Incontinence (ICI) Guidelines, a grade C recommendation has been given to SNS as a second line therapy for patients suffering from sphincter defects of greater than 180 or major perineal tissue loss, if initial reconstruction could not be performed, or failed and incontinence persisted. More information from randomized trials is required to clarify the role of SNS in treating fecal incontinence.

Artificial bowel sphincters. Prosthetic sphincters have been used for incontinence for more than 30 years for urinary incontinence with an excellent success rate that exceeds 90%.[27] The ABS was adapted from the artificial urinary sphincter (AMS 800) and introduced in 1972 by the American Medical System (Minnesota, USA) for the treatment of patients with severe fecal incontinence. Christiansen et al[28] in 1987, were the first group to report the use of the AMS 800® artificial urinary sphincter for fecal incontinence with excellent results with no complications at a follow-up of 3 months. Since then, several studies and trials have emerged, studying and trying different types of ABSs and comparing them to other treatment models. Currently, there are 3 types of ABSs that have been used on patients, and several others that are still at the laboratory phase, and have not yet been launched to clinical practice. These include, the German Artificial Sphincter System (GASS), which is an entirely new experimental and high-tech sphincter made of polyurethane. It consists of a support ring including 2 cuff elements: a fluid reservoir fixed on its outer diameter and a multi chamber occluding the cuff on the inside diameter. This device was evaluated in pig's anal canals and achieved adequate continence at very low working pressures (17.5-41.4 mm Hg), thus, promising a correspondent low risk of intestinal ischemic injury, erosion, and bleeding.[29-31]

In this section, the main discussion will be on 3 clinically applied sphincters, device structure, indications and contraindications, results of clinical studies, future applications, and challenges.

Indications and contraindications for anti-incontinent prosthesis. Benign disease. The indications for the artificial sphincter are usually the same for those

of the biological sphincters, namely, DGP.[32] Candidate patients are those who are suffering from substantial anal sphincter damage that is not amenable to simple surgical repair. Examples include a sphincter complex that has become non-functional due to severe neurogenic damage, congenital disease such as anal atresia or spina bifida, or even failure of previous sphincter restoration therapies.[33] The pediatric population with such congenital anomalies as imperforated anus would benefit from treatment with the ABS where implantation of the sphincter device can be deployed at the time of the 'pull-through' operation, or many months/years later as a secondary procedure.[34-37] In addition, ABSs may be useful in managing fecal incontinence of neuromuscular origin, as in myasthenia gravis or diabetic neuropathy.[38-40]

Malignant disease. Recently, ABSs have been successfully implanted in patients who have had surgical resection of the anus, abdominoperineal resection for low rectal or anal cancer.[41] However, there should be sufficient soft tissue in the perineum to support the placement of the cuff around the new anal canal.[7,42] Only a handful of cases have been reported, possibly because of the general concern regarding the risk of cancer recurrence thus limiting the experience on this subject.

Contraindications to implantation of the ABS include active ongoing or chronic pelvic infection, radiation-induced perineal lesions, excessive perineal descent,[43] Crohn's disease, poor functional status, and receptive anal intercourse.[20,44] Patients with restrictive rectal compliance conditions resulting in chronic diarrhea, persistent fecal impaction, or those who have had previous surgeries resulting in a severely scarred perineum, or impaired vascular supply are not suitable candidates. Inability to cope psychologically, as well as overlying skin disease at the area, or pregnancy,[33] and activities, such as bike riding and horse riding have been considered as limitations to ABS implantation[20] (**Table 1**). Some authors have also considered age as a limitation and a relative contraindication, for patients who are less than 16 and older than 75 years.[42,45]

Types of anal sphincters. 1. Acticon® Artificial Bowel Sphincter. The first implantation of this new device (the Acticon® ABS, American Medical Systems, Minneapolis, MN, USA) was performed in Nantes, France, in May 1996.[46] Since this time, experience has been acquired in numerous expert centers worldwide. Three years later, the American Food and Drug Administration (FDA) approved the humanitarian use of the device after completion of a multicenter trial,[47] ever since, this has become the most commonly used device worldwide. Most clinical trials have been carried out on it. The Acticon® ABS consists of 3 main components (cuff, balloon, and pump) (**Figure 1**). All 3 parts of the Acticon® ABS are made of solid silicone elastomers that are inert with minimal to no risk of rejection by the body, totally implanted subcutaneously, and linked by subcutaneous kink-resistant and color coded tubes. The occlusive cuff is implanted around the upper part of the anal or neo-anal canal. The control pump is placed in the scrotum or labium. The pump has 2 parts; a hard upper part, which contains the resistor and valves needed to regulate the rate of fluid circulation throughout the system, and a deactivation button allowing fluid cycling to be stopped by external action. The patient squeezes and releases the soft lower part of the pump several times to transfer fluid within the system. A septum at the bottom of the control pump is designed to allow the insertion of a small amount of fluid, if needed, in the postoperative period.[48] The pressure regulating balloon

Table 1 - Clinical indications and contraindications.

Indications
Sphincter trauma
Neurologic
Idiopathic
Failure or contraindications to sacral nerve stimulation
Imperforated anus
Advanced age
Diabetes
Relative contraindications
Scarred perineum
Thin recto-vaginal septum
Handling difficulties
Absolute contraindications
Excessive perineal descent
Severe constipation
Irradiated perineum
Perineal sepsis
Crohn's disease
Anal intercourse

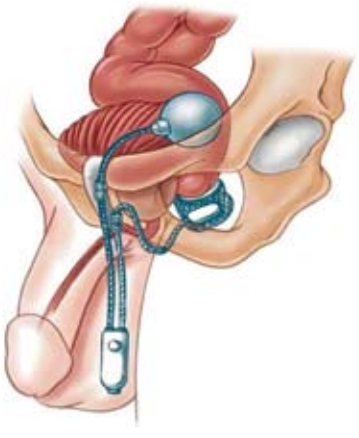

Figure 1 - Acticon® neosphincter implanted in a male. The inflatable cuff around the anal canal is connected to the control pump that is subcutaneously positioned in the scrotum, and connected to the regulating balloon, which is placed either in the prevesical space. Reproduced and published with permission of American Medical Systems, Inc., Minnetonka, Minnesota (www.americanmedicalsystems.com)

is implanted in the lower abdomen, under the muscle layer, just above the pubic symphysis, which is normally filled with a sterile solution usually saline that can be imaged with plain x-ray (**Figure 2**).[43]

2. The A.M.I. Soft Anal Band. The A.M.I. Soft Anal Band Implant (Agency for Medical Innovations GmbH, Feldkirch, Austria) is a manually operated system and is implanted subcutaneously. The system consists of 4 parts. The Soft Anal Band Implant is placed inside the surgically created circular pocket around the anal sphincter and is connected to a small and stable, domed shaped valve. When the valve is activated, liquid flows back from the band to the activator, which is a strong and reliable silicone balloon. By applying pressure (with the palm of the hand) on the skin above the activator, liquid flows back into the band resulting in closing the anal band; thus, continence is achieved. The fluid required to obtain maximum continence is adjusted as needed through the calibration port (**Figure 3**). The anal band ring should be left open for 6 weeks to assure optimal healing before activating it.[49,50]

3. Prosthetic Anal Sphincter (PAS®). (NPH Design Ltd. Pavilion Road, London, UK) The device was first introduced to the market at the Tripartite Colorectal Conference in Dublin in July 2005 (http://www.ihe-online.com/index.php?id=1186&tx_ttproducts_pi1%5Bproduct%5D=3329), after passing the approval of the European Community regulations and the Medical Devices Agency. This device was designed to overcome the ischemic complications associated with other models.[51-53] It is devised to simulate the normal physiology of the ano-rectum, reproducing the action of the puborectalis muscle by flattening and angulating the bowel without causing crenation. Therefore, it reflects the normal action and function of the anal sphincter and pelvic floor muscles,[54] reproducing the action of the puborectalis muscle. The sphincter consists of 4 parts, 3 parts are implanted intra-peritoneally, an inflatable linear expander, a soft gel-filled pillow, and a balloon reservoir, all are placed around the bowel at the level of the anorectal junction. The control pump is subcutaneously placed in the right iliac fossa where it is manually operated by the patient. Pumping transfers fluid within the system. The device is activated 6 weeks after surgery.[54]

Clinical results. Success rate and functional results. Success rates for the artificial sphincter vary from 49-82%,[20,55] based on clinical assessment, enhancement in quality of life, and a high degree of safety.[19,47,56] However, direct comparison of continence outcomes across studies is difficult owing to the use of 3 different continence measurement systems: the Williams, the AMS and the Cleveland Clinic Continence scales (Wexner incontinence scores).[47,57-59] Unfortunately, not

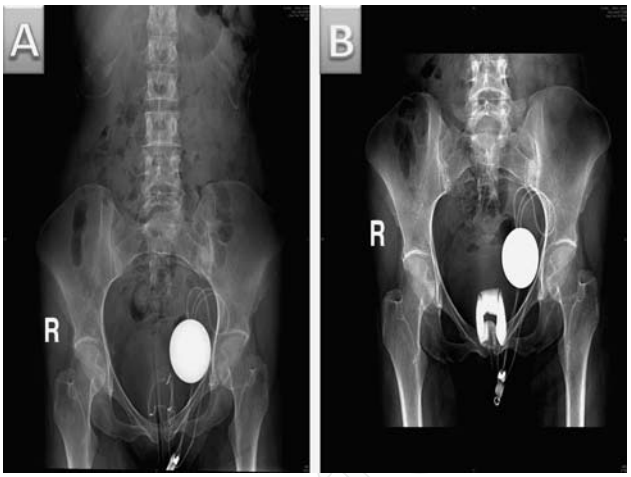

Figure 2 - Abdominal x-ray of Acticon® neosphincters in situ showing: **A**) at rest, and **B**) in closed status.

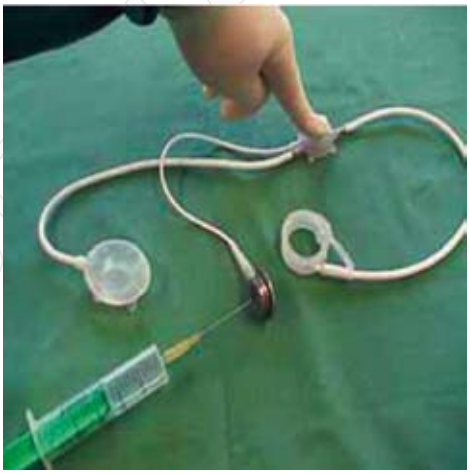

Figure 3 - The A.M.I. Soft Anal Band Implant is a manually operated system that is implanted subcutaneously. Twenty ml of sterile water is needed to achieve proper closing pressure. Reproduced and published with permission of the Agency of Medical Innovations (A.M.I.) (http://www.ami.at)

all studies presented fecal incontinence scores before and after implantation, as well as statistical analysis not conducted on an intention-to-treat basis (except one study[47]). **Table 2** summarizes the clinical trials results, assessing continence after the device was implanted. Most studies have also shown an increase in resting pressure after artificial anal sphincter implantation. However, changes in squeeze pressures were more equivocal.[55] Wong et al[47] implanted 112 Acticon® ABS's in a multicenter cohort study. Eighty-five percent had a functioning device and improved from a mean baseline incontinence score of 106 to 54 postoperatively. Continence rates after Acticon® ABS implantation remarkably improved to between 75-100% for solids, and 50-66% for gas. Parker et al[60] identified 2 patient

groups: the first who received implants before 1992 (n=10; mean follow-up, 91 months) and the other, those who received implants between 1995 and 2001 (n=37; mean follow-up, 39 months). The overall success rate in the former group was 60% (4/10 explants). The latter group had an overall success rate of 49%. Those patients who had successful implantation procedures enjoyed a 100% functional success rate at 2 years.[60] Finlay et al[54] used the PAS in 12 patients with severe fecal incontinence, which was placed in the pelvis around the anorectal junction via a transabdominal approach. At a median follow-up of 59 (range 30-72) months, 9 of the 12 patients had a functioning PAS. The PAS was effective in restoring continence in 10 of 11 patients. Median (range) Cleveland Clinic continence scores improved from 16 (7-20) before to 3 (0-7) after implantation with a corresponding score of 3 (range 0-7) at one year after activation. The PAS has a comparable continence rate of 91% (10 of 11 patients) to Acticon® ABS. The AMI Soft Anal Band was used by a German group led by Baumgartner[61] on 14 patients (10 female) with severe fecal incontinence; all failed optimum conservative treatment with biofeedback, and 9 failed the sacral nerve stimulation trial. The mean patient age was 59 years (39-71), mean duration of follow up was 13 months (3-40). Self-reported quality of life improvement of 70-100% was reported in 7/14 patients, 30-70% improvement in 4/14 (no data was available in 3/14).[62] Wexner incontinence scores improved from a median of 16 (12-18) pre treatment to 2 (0-6) post operatively (p<0.0001). However, we still await the publication of their work.

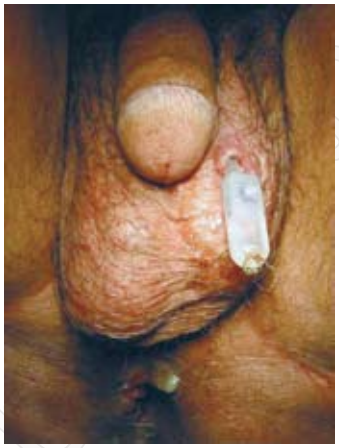

Figure 4 - Erosion of the control pump through the scrotum. (Romano G, Bianco F, Ciorra G. Total Anorectal Reconstruction with an Artificial Bowel Sphincter. Rectal Cancer Book. Milan (Italy): Springer; 2005). Published with permission from Springer Science + Business Media

Table 2 - Summary of the functional outcome of studies reporting continence gradient.

References	Year	n	Mean age, years	Follow up, months Mean (range)	Continence grading scale		
					Before implantation Median (range)	After implantation Median (range)	*P*-value
Cleveland clinical scale							
Baumegranter[61]	2009	14	59	13 (3- 40)*	16 (12-18)*	2 (0-6)*	0.001
Da Silvaa[35]	2004	11	25.3	20.4 (5-68.4)	18.5	7.5†	<0.01
O'Brien[65]	2004	7	66	6 (0)	19 (1.2)	4.8 (4.0)	<0.001
Finlay[54]	2004	12	47	59 (30-72)*	16 (7-20)*	3 (0-7)*	NR
Ortiz[66]	2003	8	34.4	44 (13)	16 (6.75)	8 (14.65)	0.018
Romano[42]	2003	8	52	14 (6-28)	11.75	3.8	NR
Devesa[55]	2002	53	46	27 (7-55)†	17 (1.8)	4.5 (3.4)	0.001
Ortiz[67]	2002	22	47	26 (6-48)†	18 (14-20)†	4 (0-14)†	0.001
Altomare[64]	2001	28	58	19 (7-41)†	15 (11-20)*	3 (0-6)*	<0.001
O'Brien[68]	2000	13	44	not reported	19 (1.6)	2 (2.6)	<0.001
Lehur[56]	1998	13	40	30 (5-76)†	17 (1.8)	4.5 (3.4)	<0.001
Vaizey[37]	1998	6	53	10 (5-13)†	19 (0.8)	4.5 (4.9)	0.001
AMS scale (Fecal incontinence scoring system)							
Casal[69]	2004	10	56	29 (9-56)†	99.9 (83-120)†	28.4 (0-58)†	<0.001
Parker[60]	2003	47	39.5	91	103 (74-120)	59 (0-108)	<0.001
Lehur[63]	2002	16	43	25 (7-49)†	105 (14)	23 (22)	<0.05
Michot[36]	2003	37	51.1	34 (7-60)†	100	63.1	NR
Wong[47]	2002	112	49	12	106 (71-120)†	48 (0-108)†	<0.001
Lehur[43]	2000	24	44	20 (6-35)†	106 (13)	22 (25)	<0.001
Dodi[70]	2000	8	56	11 (4-23)†	96 (12-0)*	19.4 (19.3)*	<0.004
Williams scale							
Christiansen[57]	1999	17	46	84 (60-120)†	5 (0-0)	2.5 (0.9)	<0.001

Values of continence grading scale are means (standard deviation) unless indicated, *median range, †means (range). NR - not reported

Complications. A wide range of complications had been reported from a minor wound infection to a major complication that necessitated device explanation and creation of permanent colostomy. Comparison among studies is difficult (**Table 3**), because of different devices, and different continence scores.

Infection. Infection remains the main harbinger of device failure with rates of 4-60% (**Table 3**).[37,43,47,55,56,63-67,69] This high rate is believed to be partly because of the implantation of a foreign object in the anorectal region.[58] Most of the studies reported postoperative infections in the perineal or abdominal surgical site before the device activation.[35-37,42,43,47,54,55,57,60,64,67-72] The risk of infection is substantial in those with existing stomas, skin conditions, impaired immunity, and diabetes.[48,74] Nonetheless, after activation many infections were caused by erosion of the device and resulted in explantation.[35-37,42,43,47,54,55,57,60,64,67-70,72]

Erosion or ulceration. Erosion and ulceration (**Figure 4**) occur as a result of ongoing sepsis, improper size, or positioning of the device, prior tissue damage from radiation and skin conditions. Unfortunately, explantation owing to erosion is a common outcome at a rate of 36%.[47,55,73,75,76]

Chronic pain. Chronic pain had been reported in almost half of the studies in a rate ranging from 4-17%, mostly occurring after device activation.[19,47,55,56,64,67,68,77]

Constipation/fecal impaction. These 2 common problems are usually resolved by a combination of dietary modification and use of oral laxatives. However, occasionally regular enemas may be required as described by Lehur and colleagues,[56] 6 of 13 patients experiencing obstructed defecation that required regular enemas. Postoperative fecal impaction rates ranging from 6-83%[37,57] have been reported in 6 studies that used the Acticon® device.[37,47,55-57,68]

Mechanical failure. This is nearly always an implantation technical issue, given that less than 3% of all mechanical failures are attributed to the device itself. These can usually be surgically revised with a high success rate.[78] This mechanical failure is in the majority because of inadvertent blocking or kinking of the tubing system or fluid leakage from accidental damage causing inadequate balloon pressure. Wear and tear of the device parts that may include control pump failure, disconnection of its prime components, or even damage from repeated trauma, all these are reasons for device failure.[79]

Table 3 - Complication rates following device implantation.

References	Year	Device type	n	Mean age, years	Constipation/ Fecal Impaction (total)	Infections (total)	Erosion (total)	Mechanical Failure (total)	Revisions (total)	Explants/ Reimplants (total)	Functioning devices (total)	Success(%)
Baumegranter[61]	2009	A.M.I. Soft anal band	14	59	1 (7.1)	0	0	5	5	0/0	14	64
Da Silvaa[35]	2004	Acticon	11	25.3	3 (38)	1	0	1	1	0/0	11	80
Altomare[72]	2004	Acticon	28	58	8 (29)	7	7	3	6	0/0	21	66
Casal[69]	2004	Acticon	10	56	1 (10)	2	3	2	4	3/2	9	90
O'Brien[65]	2004	Acticon	7	66	2 (14)	0	2	0	3	1/0	6	77
Finlay[54]	2004	PAS®	12	47	2 (17)	3	0	2	5	3/0	9	not reported
Ortiz[66]	2003	Acticon	8	34.4	2 (25)	0	4	4	5	4/1	5	20
Parker[60]	2003	Acticon	45	39.5	5 (11)	12	0	18	25	22/2	25	12
Romano[42]	2003	Acticon	8	52	3 (38)	1	0	0	0	0/0	8	63
Michot[36]	2003	Acticon	37	51.1	7 (19)	5	5	5	8	11/2	28	78
Devesa[55]	2002	Acticon	53	46	11 (22)	10	9	2	16	10/6	26	60
Wong[47]	2002	Acticon	115	49	30 (26)	38	24	7	73	34/9	75	53
Ortiz[67]	2002	Acticon	22	47	2 (9)	3	5	2	6	9/2	15	40
Lehur[63]	2002	Acticon	16	43	5 (31)	0	1	0	2	4/1	12	75
Altomare[64]	2001	Acticon	28	58	15 (54)	5	2	1	1	7/0	21	75
Lehur[43]	2000	Acticon	24	44	9 (38)	1	3	3	9	8/3	19	18
Dodi[70]	2000	Acticon	8	56	2 (25)	2	1	0	0	2/0	6	60
O'Brien[68]	2000	Acticon	13	44	not reported	2	2	0	4	3/1	10	77
Christiansen[57]	1999	AMS 800	17	46	2 (12)	18	2	41	6	7/0	8	47
Lehur[56]	1998	Modified AMS/ ABS	13	40	6 (46)	1	1	1	1	4/2	11	84
Vaizey[37]	1998	Modified AMS	6	53	not reported	2	1	0	1	1/0	5	83
Wong[19]	1996	Acticon	12	33	not reported	2	0	3	7	5/4	9	75
Christiansen[73]	1992	Modified AMS	12	50	2 (17)	3	0	4	8	2/0	10	83
Christiansen[38]	1989	AMS 800	5	50	1 (20)	2	0	1	3	1/0	4	60

PAS - Prosthetic Anal Sphincter, AMI - Agency for Medical Innovations, AMS - American Medical Systems

Recurrent incontinence. The true rate of recurrent incontinence with the device in situ is not known. There is no universally agreed upon definition of recurrent incontinence with the device in situ. In fact, many patients are highly motivated and determined to avoid a colostomy at any cost. This leads them to ignore reporting variable degrees of incontinence. Nevertheless, the various validation tools in use, to measure fecal incontinence, are subjective and not uniform.[79]

Surgical revision, explantation, and re-explantation. The rate of surgical revision ranged from 2 of 16,[63] to 6 of 12.[19] Revision surgery with replacement of a part of or the entire device occurred in between 7-25% of patients (**Table 3**).[48] Several leading causes to explantation have been identified that include perioperative infection, failure of wound healing, erosion of part of the device through the skin or the anal canal,[47,55,75] late infection, and mechanical malfunction of the device due to cuff or balloon rupture. The overall incidence of permanent explantation of the ABS varied between 17-31% in follow-up periods of between 10-58 months.[48] Even with improved experience, there is a fairly constant explantation rate of 31-33%, although the revision rate has improved.[75,80] Numbers of device explantation increases with time mostly due to device related problems. However, studies failed to identify any precise predictive patient-related factors leading to device explantation.[76]

In conclusion, in the face of living the rest of your life with a permanent colostomy, the use of artificial sphincters for end-stage fecal incontinence or following rectal excision for cancer is an acceptable management strategy to obtain continence and restore anal defecation. Despite the high morbidity associated with these device implantations, they significantly improve control of defecation and thus, improve QOL for the incontinent patient. Selection of patients is mandatory to achieve best results; operator experience is also very important in the successful outcome of the procedure. Patients' incapability to perceive when to defecate adds restraints on the wide applicability of artificial anal sphincter implantation, so they must be trained to establish the habit to defecate after the device has been implanted. Therefore, a novel artificial anal sphincter system is needed to simulate the normal physiology of the human anorectum based on transcutaneous power delivery. There are some doubts regarding the safety and the effectiveness of these prostheses owing to the low-level of evidence that is available, making one conclude that there is limited or uncertain benefit from implanting these devices. However, to have an accurate and unbiased evaluation on the use of the ABS's, will be possible only when research follows well-defined standards regarding the study design, together with short- and long-term outcome data on an intention to treat basis. Applying strict rules will result in obtaining standardized data leading to significant evidence-based conclusions.

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