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ORIGINAL CONTRIBUTIONS

Artificial Anal Sphincter

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PURPOSE: This study was undertaken to evaluate the use of a fully implanted artificial anal sphincter for management of severe fecal incontinence. METHODS: An artificial anal sphincter was implanted in 12 patients who failed conventional management for severe fecal incontinence. Careful patient follow-up was recorded during a mean 58-month follow-up. Patients underwent preoperative and postoperative manometric assessment. Functional and patient satisfaction evaluations were obtained by mailed questionnaire. RESULTS: Three infections and three mechanical complications occurred in four patients (33 percent). A successful outcome was achieved in nine patients (75 percent). Postoperative manometric studies documented establishment of an elevated high-pressure zone compared with preoperative resting pressures. Seven patients returned a detailed functional assessment and patient satisfaction questionnaire at a mean of 40 months postsphincter activation. All seven patients reported continence to solid stool. Two patients had some problems with control of liquid stool, and three had occasional incontinence to flatus. Six of the seven patients rated their bowel control as good to excellent. All seven respondents were satisfied with their functional improvement. CONCLUSIONS: Early experience with an artificial anal sphincter has demonstrated that continence can be restored with acceptable morbidity in patients with severe fecal incontinence. [Key words: Fecal incontinence; Anal incontinence; Artificial anal sphincter; Surgical technique]

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Fecal incontinence can be a distressful, incapacitating disorder that can devastate the lives of afflicted individuals. Many patients can be successfully managed by medical measures; however, for those with more severe incontinence, nonoperative treatment cannot restore a normal lifestyle. Some patients can have continence restored by surgery.[1] The best candidates for successful repair are those who have sustained a traumatic sphincter disruption.[2,–4] Variable and less satisfactory results, however, have been achieved by surgery for patients with idiopathic or neurogenic incontinence. Patients who fail medical and surgical options often face the distressing prospect of living with their incontinence or undergoing a diverting stoma. Recently, however, two new surgical procedures have been reported that might provide hope for patients who fail conventional management of fecal incontinence. Electrically stimulated gracilis muscle transposition has shown initial promise and is currently undergoing evaluation and development.[5] Successful use of an artificial anal sphincter has been reported by Christiansen and co-workers.[6–8] This report describes the combined experience at the University of Minnesota and the University of Edinburgh with the use of a fully implantable artificial anal sphincter in 12 patients who failed conventional management of fecal incontinence.

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MATERIALS AND METHODS

The artificial anal sphincter is a modification of the AMS 800® urinary sphincter made by American Medical Systems (AMS, Minneapolis, MN; Fig. 1). Modifications were made to the urinary sphincter to adopt it for use around the anus for fecal incontinence. The device is comprised of three silastic components:

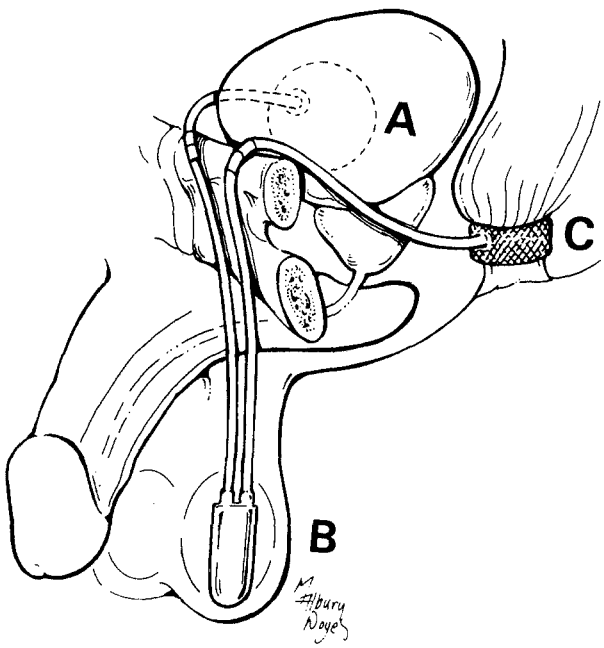

Figure 1. Artificial anal sphincter in place in a male patient. Cuff is around the anus, control pump is situated in the scrotum, and pressure-regulating balloon is sited in the Retzius' space. All components are connected by silastic tubing. (Reprinted with permission from: Wong WD, Rothenberger DA: Surgical approaches to anal incontinence. *Neurobiology of Incontinence*, Wiley, Chichester (Ciba Foundation Symposium 151) 1990:246–266.)

1) an inflatable cuff; 2) a pressure-regulating balloon; 3) a control pump. The cuff is available in 2 to 2.5 cm widths with lengths varying from 9 to 14 cm. The pressure-regulating balloon is available in several pressure ranges varying from 60 to 90 cm of water pressure. The control pump is a sophisticated device that can be activated or deactivated.

The inflatable cuff is implanted around the anus and is connected by silastic tubing to the control pump implanted in the scrotum of men and in the labia of women. The control pump is connected to the pressure-regulating balloon implanted in the Retzius' space. The system is filled with an optimum volume of fluid. In its activated state, the cuff is distended with fluid to occlude the anus and maintain continence. Cuff pressure is maintained by the pressure-regulating balloon. When the patient experiences the urge to defecate, the control pump is compressed several times, which displaces fluid out of the cuff and into the pressure-regulating balloon. This empties the cuff, thereby, decreasing anal pressure and allowing defecation to occur. The control pump then regulates slow return of fluid from the balloon to the cuff during a seven-minute to ten-minute time span, thus restoring continence. If more time is necessary for defecation to occur, the pump can be simply intermittently compressed or, alternatively, once the cuff is emptied, compression of a deactivation button on the control pump will lock the components and prevent movement of fluid. This deactivated, cuff-deflated state is used for periods of rest, particularly after implantation.

Twelve patients, seven men and five women, with an average age of 33 (range, 15–52) years underwent implantation of the artificial anal sphincter between 1989 and 1992. Causes of incontinence are listed in Table 1. All patients had previously failed conventional treatment methods. All patients underwent preoperative physiologic assessment including anal manometry. Patients with intact gastrointestinal tract continuity (5 patients) underwent a full mechanical and antibiotic preparation with a polyethylene glycol lavage solution plus oral neomycin and metronidazole. Gentamicin and ampicillin/sulbactam were administered intravenously one hour preoperatively. The seven patients with pre-existing stomas underwent modified preparation with a clear liquid diet, oral magnesium citrate, and intravenous gentamicin and ampicillin/sulbactam preoperatively. All patients gave informed consent as to the experimental nature of the procedure and were apprised of the potential risks and complications. Institutional review board approval was granted through United Hospital, St. Paul, Minnesota, for patients who underwent surgery in the United States.

Procedure and Technique

Patients were placed in the modified lithotomy position with legs in the Allen® (Allen Medical Systems, Bedford Heights, OH) stirrups with the lower portion of the operating table retracted. The five patients without a stoma first underwent creation of an end left-sided colostomy (4 sigmoid, 1 transverse). Immediately following creation of a stoma, the rectum was irrigated with a dilute povidone-iodine solution. Patients with a pre-existing stoma underwent a similar

Table 1.
Etiology of Incontinence (no. of patients)

Birthing injury	4
Major trauma	3
Imperforate anus	2
Spina bifida	1
Spinal cord tumor	1
Multiple laminectomies	1

on-table preparation. The lower abdomen and perineum were prepared and draped in continuity for a synchronous implantation procedure.

The cuff was inserted around the anus through two 3-cm-long pararectal incisions extending high into the ischiorectal fossa to the inferior surface of the levator muscles. At this level, anterior and posterior tunnels were created to allow circumferential placement of the cuff. Concomitantly, a Pfannenstiel's incision was made, and a pocket large enough to accommodate the pressure-regulating balloon was created in Retzius' space. Tubing of the cuff was tunneled subcutaneously along the perineum from the perianal area to the subcutaneous tissue of the Pfannenstiel's incision wound. Blunt finger dissection was used to create a pocket in the scrotum of the man or the labia majora of the woman. The control pump was then placed into this pocket and carefully positioned to assure ease of palpation of the control pump and the deactivation button. Connecting tubing was tunneled from the control pump to the Retzius' space. An appropriate volume of diluted radiopaque fluid (Hypaque®, Sanofi, Winthrop Pharmaceutical, New York, NY) was instilled into the component parts (50 ml of Hypaque®, 25 percent in 60 ml of sterile water). Tubing from the balloon and that from the cuff were connected to the appropriate tubing of the control pump that had previously been placed into the scrotum or labia. All wounds were irrigated and meticulously closed (Fig. 1). Manometric pressures with the cuff activated and deactivated were recorded. A Stryker® (Stryker Instruments, Kalamazoo, MI) manometer with microballoon was used for these intraoperative recordings.[9] The system was then left in the deactivated state.

Postoperative Care

Intravenous antibiotics were continued for 48 hours postoperatively. Average length of stay was 7.7 (range, 5–18) days. Patients were examined three weeks postoperatively in the office and then reassessed in the anorectal physiology laboratory at six weeks. At that time, the sphincter was activated and baseline manometric studies were recorded using a standard water perfusion system. The patient was instructed in sphincter activation and deactivation, and a protocol for progressive lengthening of the period of activation was initiated. Colostomy closure was performed an average of 19 (range, 9–36) weeks later. For five to ten days after colostomy closure, the cuff was left deactivated to allow anastomotic healing to occur without distal obstruction. The patient was then instructed to resume the activation/deactivation protocol. In general, the sphincter was left activated during the day but deactivated at night to minimize risk of pressure injury to the anal canal. Manometric re-evaluation was performed on nine patients at an average of 15 months postactivation. Patient satisfaction and functional assessment questionnaires were completed by seven patients at a mean of 40 (range, 20–58) months postactivation.

RESULTS

Morbidity

Of the 12 patients, 10 had surgery at the University of Minnesota and two had surgery at the University of Edinburgh, Scotland. Mean follow-up was 58 (range, 30–76) months postimplantation.

There was no mortality but morbidity occurred in four patients (33 percent) because of infectious complications (3 patients) and mechanical problems (3 patients; Table 2). Two infections occurred in the perioperative period, and one occurred remotely (8 months). One of three patients who developed an infection was treated successfully with antibiotics and delayed wound closure, but two required explantation and a stoma to control the sepsis and inconti-

Table 2.
Complications

Patient No.	Complication	Consequence	Salvage (follow-up mo)
2	Infection	Explanted/reimplanted	Yes (51)
4	Cuff leak	Explanted/reimplanted	Yes (43)
11	Infection	Antibiotics/delayed closure	Yes (42)
	Leak balloon	Explanted/reimplanted	Yes (30)
	Leak pump	Explanted/reimplanted	Yes (1)
12	Painful location	Relocated	Yes (4)
	Infection	Explanted	No

nence. In one person, patient 2, the implant was performed initially without a stoma. A successful reimplantation was performed under cover of a temporary stoma 16 months later. The other patient chose to live with a permanent stoma. The four mechanical problems occurred at a mean of 32 (range, 5–48) months after the first implant. Of these, cuff leak (1), balloon rupture (1), painful tubing implant site (1), and pump leak (1) were remedied by reoperation without reconstructing a stoma.

Functional Results

A successful outcome was achieved in 9 of 12 patients (75 percent; Table 3). All nine successful patients at last follow-up have achieved significant improvement in their continence. Three of 12 patients are failures. One developed both an infection and a mechanical complication as described above and chose not to undergo a reimplant. The second patient, despite having no infectious or mechanical complication and having achieved a reasonable functional result, demanded explantation in the hope that this would resolve his chronic back pain, pre-existing sexual dysfunction, and other psychologic problems. The third patient had reasonable function initially but redeveloped incontinence to liquid stool and gas and had a stoma re-established after nearly four years.

Ten patients were evaluated both preoperatively and at activation by a water perfusion anal manometry testing system. Average preoperative resting pressures were 16 mm of mercury. After activation of the artificial sphincter, average activated pressures increased to 68 mm of mercury (Fig. 2). Nine patients had follow-up manometric testing at an average of 15 months after activation, and the high-pressure zone was reasonably well maintained, although some loss of pressure occurred in five patients (Fig. 3). Recently, our first patient, now six years since implant, noted some deterioration in function with occasional incontinence of gas. The addition of 3 ml of fluid percutaneously instilled *via* an access port on the control pump successfully restored complete continence.

Table 3.
Outcome (N = 12)

	No.	%	Mean Follow-up (mo)
Successful	9	75	48
Failure	3	25	32

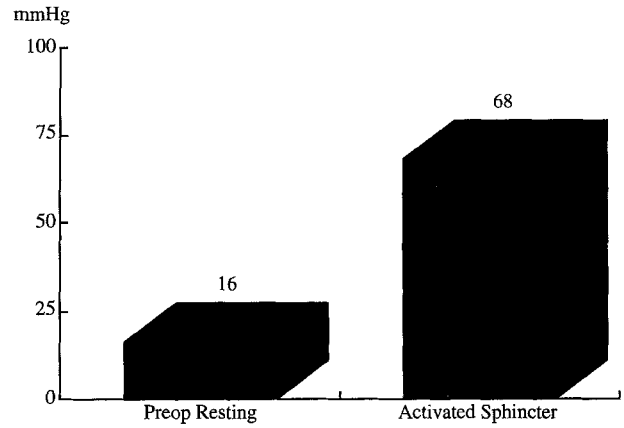

Figure 2. This demonstrates the static high-pressure zone that is created by the activated sphincter compared with preoperative mean resting pressure in ten patients.

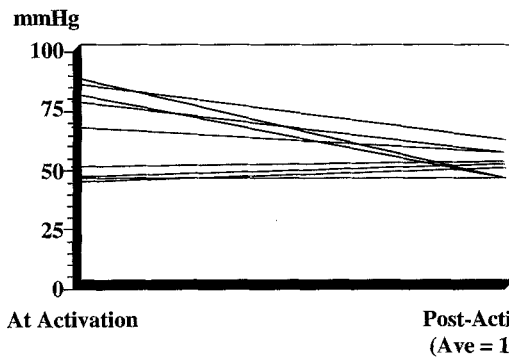

Figure 3. Each line, which represents one of nine patients, demonstrates that mean high-pressure zone created by the artificial sphincter is maintained after 15 months have elapsed since activation. Ave = average.

Table 4.
Incontinence (no. of patients)

	Daily	Weekly	Rarely	Never
Gas	1	2	1	3
Mucus	2			5
Liquid stool	2		3	2
Solid stool			1	6

Seven of nine patients achieving successful results returned a detailed functional assessment and patient satisfaction questionnaire at a mean of 40 months following activation of their artificial anal sphincter and form the basis for this functional assessment. The two patients, both from the United Kingdom, who failed to respond to the questionnaire are reportedly continent and very satisfied with their status. Of the seven respondents, all are continent of solid stool, whereas two have problems with control of liquid stool and three have occasional incontinence of gas (Table 4). Only two of seven patients say they expe-

rience occasional lifestyle alterations as a result of their function. This is detailed in Tables 5 and 6. Two patients frequently still wear a pad (Table 7). Three patients routinely use anti-diarrheal agents to improve function. All seven patients either always or usually can sense an impending evacuation and can reach a toilet in time. Six of seven patients considered themselves to have good to excellent control. Only one patient rated her control as poor but indicated that she was much improved compared with preoperatively and remains satisfied with her device (Table 8).

DISCUSSION

Success of the artificial urinary sphincter, which was first implanted in 1972, stimulated our interest in a similar device being used for control of fecal incontinence.[10, 11] Preclinical investigations have been performed in animal models using an inflatable artificial sphincter prosthesis on bowel, generally around established ileostomies.[12, 13] These studies showed that the implantation of these devices is straightforward and that cuff pressures in the range of 50 to 70 cm of water were generally well tolerated by the ileum for several months without infection, erosion, or other adverse sequelae. In these animal models, a satisfactory degree of continence was achieved. However, when devices were placed intraperitoneally, adhesions to the capsule of the device occurred.

Various clinical studies have assessed a mechanical cuff placed around a colostomy. Heiblum and Cordoba[14] in 1978 described a subcutaneous cuff that was placed around a colostomy and inflated by the patient using an external syringe. They used this device in six patients, five of whom had successful results; however, one device had to be removed because of infection and erosion. All patients apparently were continent to gas and solid stool. Szinicz[15] implanted a similar device in seven patients. Early work using the 800 AMS® urinary sphincter on bowel was described in an attempt to restore continence for urinary diversion patients. In 1984, Light and Scott[16] described the use of this device in four patients with implantation around the outlet of a neobladder made from sigmoid colon. In 1987, Burbige *et al.*[17] reported placement of the urinary sphincter around bowel segments in nine reconstructed bladder exstrophy patients. They noted, however, that eventually eight of the nine patients in whom this was performed again became incontinent because of atrophy of the bowel under the cuff. This was thought to be caused by direct pressure of the cuff on the bowel and, after one further revision, no further progression of incontinence developed. This documentation of atrophy of the bowel under the cuff was a cause for concern in the early approach to its use for fecal incontinence. To date, this has not been a problem perhaps because the anorectal region is accustomed to a high-pressure zone in its normal state.

Table 5.
Persistent Lifestyle Alteration (no. of patients)

Not at all/rarely	5
Occasionally	2
Frequently	0

Christiansen and Lorentzen[7] reported their initial experience with five patients with neurogenic incontinence treated with an 800 AMS® urinary sphincter placed around the anus. They noted that the system worked for solid or semisolid stool but less well for diarrhea. In a subsequent report by Christiansen and Sparso,[8] their experience with 12 patients implanted with the modified artificial anal sphincter was reported. Of ten patients available for functional assessment with over six months of follow-up, five had excellent results, three had good, and two had acceptable results. Two patients developed infection necessitating removal, and four patients had eight revisional procedures.

Indications for this operation have yet to be fully defined. This series has documented that it can be successfully used for neurogenic fecal incontinence and incontinence caused by trauma to the anus resulting in sphincter disruption or avulsion. Two of the three patients in whom this operation was performed for anal incontinence secondary to severe trauma had such extensive injuries that implantation of the device could not be accomplished until soft tissue reconstruction around the anus was performed. This was achieved by dissection of the anus and distal rectum off of the posterior aspect of the symphysis pubis where it had been displaced and adherent. The resulting defect was then reconstructed by rotating a large C-flap comprised of skin and buttock soft tissue (no muscle) to recreate a soft tissue base surrounding the anus that would later accommodate an artificial anal sphincter device. In both patients, this goal was achieved, and both patients have achieved satisfactory continence after a second-stage implantation of the artificial anal sphincter and third-stage closure of their colostomy.

Patients who had the operation done for multiple

Table 6.
Lifestyle Limitations Attributable to Fear of Incontinence

Activity	Never	Rarely	Occasionally	Frequently	Impossible	Abstain for Other Reasons
Walking	2	4	1			
Vigorous exercise	3	1		1		2
Household chores	5	2				
Visiting friends	4	1	1		1	
Driving	5	1				1
Sexual relations	4	3				
Employment	3	3	1			
Travel	2	4			1	
Ability to care for self	6		1			
Shopping	4	1	1	1		

Table 7.
Ancillary Measures

	Never	Occasional	Frequent
Pad	4	1	2
Change in undergarments	2	3	2
Perianal cream	5	1	1

Table 8.
Bowel Control Self-Rating

Excellent	1
Very good	3
Good	2
Poor	1

failed sphincter repairs after birth trauma have done exceptionally well and are fully continent. To date, we have been extremely selective in our choice of patients for this experimental procedure. This early success should lead to an expansion of indications.

A learning curve is apparent in the finer details of the procedure, although overall success was achieved early in the series patients and in more recent experience. Although no erosion of the cuff has occurred, this was an area of concern because the cuff could be easily palpated perianally in our early cases. For this reason, we have placed the cuff high against the inferior aspect of the levator muscles in our more recent patients. The cuff is no longer palpable except high in the anal canal by digital anorectal examination.

Seven of 12 patients had an existing stoma at the time of sphincter implantation. The other five had a stoma created before successful initial implantation of the device. Patient 2 had a device inserted without a covering stoma. She developed a wound seroma that became infected, and she required removal of the system and creation of a colostomy. She later had a successful reimplantation of a sphincter device. This experience led us to recommend proximal fecal diversion before prosthetic implantation in all patients. One further patient who had an initial stoma that was subsequently closed developed two separate mechanical failures (cuff leak and later pump leak) but has had successful explantation and reimplantation without the re-establishment of fecal diversion in both instances.

The complication rate is 33 percent. Use of a foreign material in the perianal area raises significant concern regarding infection rate and ability to retain a foreign body in this location. Although still unanswered in the long-term, the 25 percent infection rate seen thus far is less than what was anticipated and the fact that two infections were successfully managed with eventual achievement of continence by the artificial device is very promising. Although we have advised a diverting stoma since our second patient who had the infection after implantation without a covering stoma, it is not certain that such caution is absolutely necessary. In fact, Christiansen and Sparso[8] did not use a protective colostomy in any of their 12 patients and reported only a 17 percent infection rate (2 patients) necessitating device removal. These patients, however, did not have reimplantation of the device after sepsis was cleared.

Functional results have been very gratifying and have exceeded our expectations. Of the nine successful patients who have had continence restored, all are very satisfied with their function and results to date. In fact, some are so continent of gas that, when it is necessary to pass flatus, some will often have to deflate the cuff to do so. This in itself can be an inconvenient and negative aspect, because cuff deflation usually has to be done in a private setting as a result of pump location in the scrotum or labia. Most

consider this a small price to pay for restoration of continence.

Continence appears to be restored by the simple creation of an effective static high-pressure zone by the artificial anal sphincter. We were surprised to find that relatively low levels of pressure are needed to achieve these results. This reflects our rather limited understanding of continence mechanisms.

SUMMARY

Early experience with an artificial anal sphincter has demonstrated that continence can be restored in patients with severe fecal incontinence. Long-term results are not yet available; however, this study has shown that this new procedure is simple, safe, and effective and holds considerable promise for patients with this affliction.

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