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Artificial Bowel Sphincter Implantation for Faecal Incontinence in Asian Patients

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BACKGROUND: To evaluate the outcomes with the American Medical Systems artificial bowel sphincter (ABS) implantation for the treatment of intractable faecal incontinence in an Asian population.
METHODS: Six Asian patients who underwent ABS implantation between March 2004 and December 2007 for the treatment of faecal incontinence were reviewed.
RESULTS: The ABS was successfully implanted in six patients [mean age 50 (20–73) years; 4 males]. The most common causes of incontinence were congenital anomaly of the anus (imperforate anus status post a pull-through procedure) and status-post ultralow anterior resection. Two patients required device explantation due to postoperative infection. One eventually required a colostomy. After a mean follow-up of 22 (4–36) months, four patients continued to have a functional artificial bowel sphincter. Faecal incontinence severity scores improved from a mean of 13 (12–14) to 6 (0–9) postactivation. Anal manometry showed an increase in mean resting pressures (19.2 ± 7.5 mmHg *vs.* postimplantation with cuff inflated 45.0 ± 12.0 mmHg). The comparative preoperative and postactivation faecal incontinence quality of life scores showed improvement in all aspects.
CONCLUSIONS: Patients with successful ABS implantation benefited from improved outcomes in function and quality of life. Infection was the most common cause of failure in our patients. [*Asian J Surg* 2010;33(3):134–42]

Key Words: Action, artificial bowel sphincter, Asians, faecal incontinence

Introduction

The artificial bowel sphincter (ABS) was adapted from the artificial urinary sphincter (AMS800) which was introduced in 1972 by American Medical Systems (Minnetonka, MN, USA).[1] In 1987, Christiansen and Lorentzen[2] from Denmark published the first account of its use for faecal incontinence. Their patients had excellent results with no complications after 3 months of follow-up. In 1996, the ABS was then modified as the Acticon Neosphincter device (American Medical Systems), specially designed for faecal incontinence. Wong et al[3] reported good functional results with acceptable morbidity in their early experience. This was seen as a feasible new option in the treatment of severe faecal incontinence. Numerous studies have since reported acceptable outcomes, good functional results, effectiveness and safety of this new device.[4–9] However, most of these studies were performed in western countries. There are no known reports of results obtained from Asian patients. The aim of this study was to report our experience with the ABS implantation for the treatment of faecal incontinence in this group of patients.

Patients and methods

Patients and study design

All patients presenting to the division of Colorectal Surgery at the National University Hospital with severe

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intractable faecal incontinence, which did not respond to conservative treatment or whose defects of the anal sphincter complex were deemed unsuitable for sphincteroplasty, were considered for the procedure. Evaluation with endoanal ultrasonography (EAUS), 8-channel water perfusion manometry was then performed. Only patients who were able to understand and manage the device were selected for the procedure. These patients were educated on the details of the device including its function and mechanism. Informed consent was then obtained prior to the implantation procedure. Following recovery from the implantation procedure, all patients were again evaluated using anal manometry. Two sets of readings were obtained: one with the cuff inflated and the other with the cuff deflated. The degree of continence was measured according to the Wexner continence grading score system (CGS);[10] which ranges from 0 (normal continence) to 20 (total incontinence). Assessment of the quality of life (QOL) was performed using the Fecal Incontinence Quality of Life Instrument (FIQL).[11] These were obtained preoperatively and postoperatively. The postoperative FIQL scores were obtained at least 3 months after successful implantation of the device. The FIQL questionnaire comprises 29 items assessing the four domains of quality of life: life style (10 items), coping/behaviour (9 items), depression/self-perception (7 items) and embarrassment (3 items). Each response to a specific item was assigned a value and scores for each of the four individual FIQL scales were calculated accordingly. We also used a summarized global score by taking the mean of the four scores.[11]

Operative technique

After appropriate preoperative evaluation, all patients were scheduled for elective implantation of the ABS under general anesthesia. Informed consent was obtained by the primary surgeon. Antibiotic prophylaxis using intravenous cefazolin 1 g, metronidazole 500 mg and vancomycin 1 g was administered 30 minutes prior to commencement of the operation. Mechanical cleansing of the colon was achieved by administering 2 L of poly-ethylene glycol on the day before the procedure.

Patients were placed in a high lithotomy position. The device used was the Acticon Neosphincter artificial bowel sphincter (American Medical Systems, Minneapolis, Minnesota, USA) comprising three components: the occlusive cuff, the pressure regulating balloon and the control pump.

An anterior transverse curvilinear incision was made around the anus to obtain access to the extra-sphincteric space. The AMS cuff sizer was then used to determine the required cuff length. The length of the anal canal was used to approximate the width of the cuff required. The appropriately sized cuff was then tested externally and then soaked in a gentamicin solution prior to placement around the anal sphincter complex, making sure that the fit was snug and not overly constrictive. The pressure-regulating balloon was placed in the prevesical space of Retzius via a transverse suprapubic incision. The cuff was filled with radio-opaque solution (Omnipaque; GE Healthcare Canada Inc., Ontario, Canada) and the connecting tubes were clamped. The reservoir balloon was then pressurized by filling the balloon with 55 mL radio-opaque solution and clamping inflow and outflow tubes. All the appropriate tubes were connected and the fluid was allowed to equilibrate between the cuff and the balloon. Adequate anal canal compression was assessed digitally by the surgeon. The control pump was placed in the labia majora in women and the scrotum in men. The connecting tube was tunneled subcutaneously from the suprapubic incision. We made sure that the activation button was easily palpable when sited in the scrotum or the labia majora. Radiological confirmation of the positions of all the components was obtained intraoperatively. All wounds were irrigated with povidone iodine and gentamicin solution (about 1 mg/dL concentration) before closure. Oral antibiotics (ciprofloxacin and metronidazole) were continued for 24 hours postoperatively.

All patients were reviewed in the clinic regularly for a duration of 2 months before the device was activated. This was to ensure that there was no evidence of postoperative infection. Figures 1 and 2 showed the final position of the ABS in males and females.

Results

The median duration of incontinence was 2.5 years (range: 1–20 years). The aetiology of incontinence was postsurgical in four patients (two after posterior sagittal anorectoplasty, two after ultra low anterior resection), trauma in one and peripheral neuropathy in one (Table 1). Two patients had prior medical treatment and biofeedback and another two underwent phase I sacral nerve modulation. All had failed conservative treatment.

The size of the cuff was determined by the surgeon, based on the assessment of the length of the anal canal.

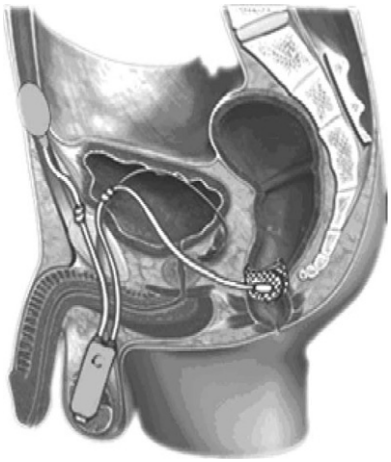

Figure 1. Position after implantation in male.

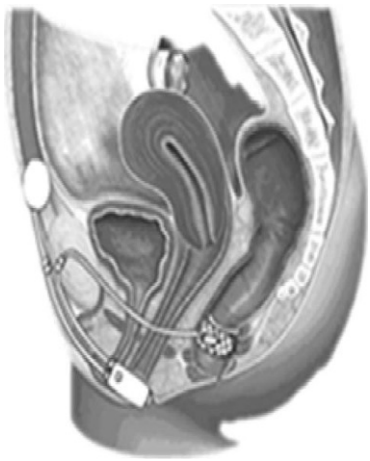

Figure 2. Position after implantation in female.

Table 1. Demographic and general data of patients

Patient	Race	Age (yr)	Gender	Cause of incontinence	Preoperative incontinence treatment	Size of cuff used (cm)	Follow-up (mo)	Operative time (min)
1	Malay	64	Female	Post ultra-low anterior resection	Ileostomy	11	0.25*	125
2	Indian	67	Female	Neuropathy	Medical treatment	9	3	195
3	Chinese	54	Male	Penetrating anorectal trauma	Colostomy	10	5	175
4	Chinese	73	Male	Post ultra-low anterior resection	Ileostomy	10	40	260
5	Chinese	22	Male	Congenital (imperforate anus status-post pull through)	Medical treatment	9	25	110
6	Indian	22	Male	Congenital (imperforate anus status-post pull through)	Medical treatment	10	25	105

*Patient developed wound dehiscence requiring explantation of the artificial bowel sphincter 1 week postoperatively.

All 6 patients were implanted with the narrow-width cuff (2 cm). The lengths of the cuffs used were 9 cm in two patients, 10 cm in three patients and 11 cm in one patient. The mean operative time was 161.7 minutes (range: 105–260 minutes; Table 1).

The median follow-up was 27 months (range: 0.25–52 months). Early postoperative infection of the perineal wound occurred in two patients. One patient developed a perineal wound dehiscence with exposure of the perianal cuff and faecal contamination of the wound within the first week. The cause of this was attributed to the incessant scratching of the healing wound by the patient, who was educationally subnormal and was unable to follow the specific postoperative instructions. This necessitated the eventual explantation of the device. The other patient's perineal wound dehisced two weeks following

Table 2. Morbidity

Patient	Complication	Time after surgery (wk)	End result
1	Cuff erosion from digital self manipulation and fecal contamination to ABS	1	Explantation
2	Cuff erosion and perianal abscess	14	Explantation
5	Wound dehiscence	2	Conservative treatment

ABS = artificial bowel sphincter.

the implantation procedure. This was treated successfully with conservative measures using local wound irrigation and oral antibiotics.

Late infection occurred in another patient at 14 weeks after implantation. He was brought to the operating room and the device had to be explanted (Table 2). This patient was of a very thin body habitus, with little bulk in his ischiorectal fossa. This was believed to be the cause of the gradual erosion of the cuff through the skin and subsequent infection. The overall explantation rate at the end of study was 33%. Of the 2 patients who required explantation, one underwent a colostomy, the other underwent a graciloplasty.

Four patients were available for long term clinical evaluation. Two patients did not have any proximal diversion prior to device implantation. Both had objective improvement in continence to liquid and solid stools as evidenced by a decrease of CGS from 12 and 14 to 9. Another patient developed the subjective symptom of constipation following activation of the ABS. This was subsequently found to be a result of the improper use of the ABS. Diet modification with re-education resulted in improved symptoms. Patients who had a successful implantation of the device in the long term showed improvements in the mean CGS scores from 13 (range: 12–14) to 6.5 (range: 0–9; Figures 3 and 4, Tables 3 and 4).

We were unable to perform the FIQL and CGS comparisons for the two patients with stomas. For the remaining patients, improvements in all scores were observed except for the lifestyle domain.

Manometric results

Mean resting anal pressure was 19.2 ± 7.5 mmHg before and 21.1 ± 5.5 mmHg (cuff deflated) after ABS implantation. The preoperative squeeze pressure was 38.2 ± 6.4 mmHg and the mean postoperative anal resting pressure with the device activated (cuff inflated) was 45.0 ± 12.0 mmHg. There was an improvement in the mean resting pressures increasing from 19.2 ± 7.5 mmHg (preoperative) to 45.0 ± 12.0 mmHg (postoperative). The mean length of the high-pressure anal zone or anal length increased from 3.0 ± 0.8 cm to 5.1 ± 0.7 cm (Table 5, Figures 5 and 6).

Discussion

The ABS has been well described in the literature as a suitable treatment option for faecal incontinence. This paper describes our experience specific to an Asian population. The results corroborate most reports in demonstrating the effectiveness of the ABS in treating intractable faecal incontinence. There were technical differences when compared to the reports from the west. Considering that most of our patients were of a smaller physical habitus, the cuff width used in all our patients was 2.0 cm (narrow cuff). This was a difference we noted when comparing with those in the western population,where more than 50 percent of the patients were implanted with a 2.9 cm cuff (wide cuff).[12] In addition, the circumference of the used cuff in the western population was larger than those in our series. (16.7% in our series *vs.* 85.7% in the Altomare study[12] with cuff circumference greater than 10 cm). These differences can be attributed to the distinctive anal anatomical differences between the two groups. The most serious complication of the implanted ABS in our patients was infection and/or erosion. The risk of infection is naturally increased owing to the implantation of a foreign object in the anorectal region.[13] The incidence of infection following ABS implantation has been reported to be 4–40%.[6] Both the perineal and abdominal surgical site may be involved in early infection (before activation of ABS) despite the routine administration of perioperative antibiotics and strict aseptic intra-operative measures. Following activation, most infections are caused by the

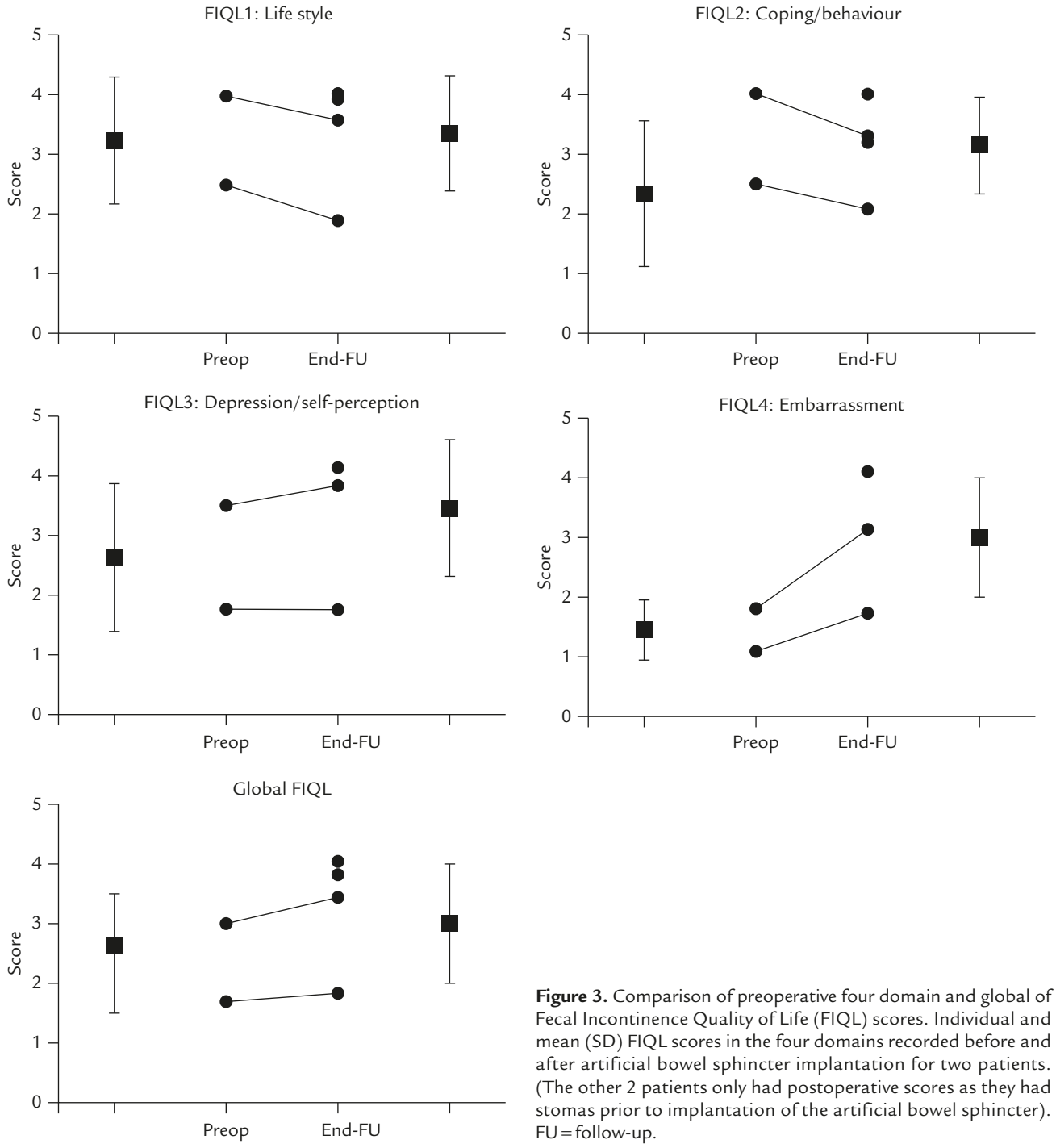

Figure 3. Comparison of preoperative four domain and global of Fecal Incontinence Quality of Life (FIQL) scores. Individual and mean (SD) FIQL scores in the four domains recorded before and after artificial bowel sphincter implantation for two patients. (The other 2 patients only had postoperative scores as they had stomas prior to implantation of the artificial bowel sphincter). FU = follow-up.

erosion of the device through the perineal wound necessitating explantation.[6] However, we observed that our patients have comparably less ischiorectal fat which may potentially increase the risk of cuff erosion. The overall rate of infection in our series was 50%; three of the six patients—two were severe and required the device to be explanted, the other patient had minor infection with wound dehiscence and was successfully treated conservatively. The rate of explantation ranged from 16.7% after a mean follow up period of 10 months in the Vaizey et al study[14] to 41.2% after a mean follow-up period of 5 years.[5] The definitive explantation rate, which is described as the permanent removal of the device[3,15,16] was 33.3% in our series. The recent Cochrane review has revealed evidence showing that the ABS is superior to conservative treatment in improving faecal incontinence. However it is associated

with a high incidence of significant morbidity (OR 11.67; 95% CI 0.48–282.04).[17] Lehur et al[16] used the FIQL scores to assess the quality of life in 16 implanted patients. They demonstrated significant improvements of the FIQL scores and anal incontinence (FIS) scores.[4] This was comparable to that of our patients, where the FIQL scores were superior in all classes except for class 1 (Table 3, Figures 3–6). Table 6[14,16,18,19] summarizes the results of continence grading scale in previous studies. The improvements in CGS scores between our preimplant and postimplant patients were comparable to previous reports in the Western population.

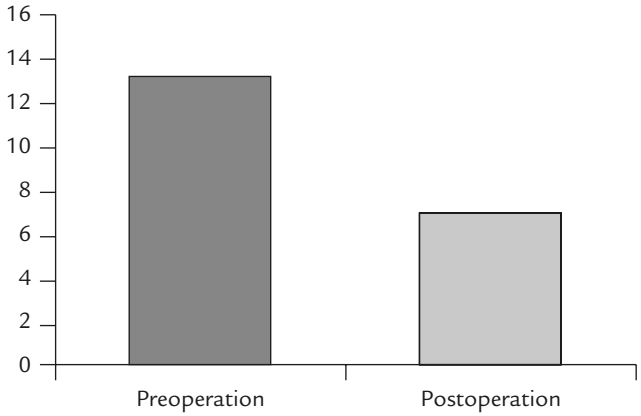

Figure 4. Mean Continence Grading Scores preimplantation and postimplantation.

A major concern with this device is the risk of ensuing obstructed defecation. In our series, only one elderly patient complained of constipation and impaired evacuation after implantation. Altomare et al[12] reviewed 28 patients and found that over half of the patients complained of some degree of difficulty in defecating and one-third had to depend on daily enemas. Similar findings were reported by Lehur et al[16] and by Devesa et al[15] with obstructed defecation found in 29% and 22% of patients respectively. We found that the reason for this outcome in our patients

Table 3. Preoperative and postoperative quality of life according to Fecal Incontinence Quality of Life (FIQL) and severity incontinence score according to Continence Grading Score

Patient preoperation	Ostomy	FIQL1	FIQL2	FIQL3	FIQL4	Global	Severity
3	Colostomy	NA	NA	NA	NA	NA	NA
4	Ileostomy	NA	NA	NA	NA	NA	NA
5	No	4	3.2	3.4	1.7	3.1	14
6	No	2.5	1.5	1.7	1.0	1.7	12
	Mean ± SD	3.25 ± 1.06	2.35 ± 1.20	2.55 ± 1.20	1.35 ± 0.49	2.38 ± 0.99	13 ± 1.4
Patient postoperation							
3		4	3.2	4	4	3.8	4
4		4	4.0	4	4	4	0
5		3.6	3.3	3.7	3.0	4	9
6		1.9	2.1	1.7	1.6	1.8	9
	Mean ± SD	3.38 ± 1.00	3.15 ± 0.79	3.35 ± 1.11	3.15 ± 1.14	3.26 ± 0.99	5.5 ± 4.4

NA = not available.

Table 4. Comparison between quality of life according to Fecal Incontinence Quality of Life (FIQL) and severity incontinence score according to Continence Grading Score

	Ostomy	Comparison between preoperation and postoperation scores					
		FIQL1	FIQL2	FIQL3	FIQL4	Global	Severity
3	Colostomy	NA	NA	NA	NA	NA	NA
4	Ileostomy	NA	NA	NA	NA	NA	NA
5	No	–0.4	0.1	0.3	1.3	0.9	–5
6	No	–0.6	0.6	0	0.6	0.1	–3

NA = not available.

Table 5. Manometric results

Patient	Preoperative resting pressure (mmHg)	Preoperative squeezing pressure (mmHg)	Postoperative resting pressure (Cuff deflated; mmHg)	Postoperative resting pressure (Cuff inflated; mmHg)	Preoperative anal length (cm)	Postoperative anal length (cm)
3	8.1	30.3	25.9	47.9	3	4.1
4	25	38.8	17.3	31.6	2.1	5.1
5	21.5	46	15.5	56	4	5.5
6	22.1	37.6	25.8	59.9	3	5.7
Mean ± SD	19.2 ± 7.5	38.2 ± 6.4	21.1 ± 5.5	45.0 ± 12.0	3.0 ± 0.8	5.1 ± 0.7

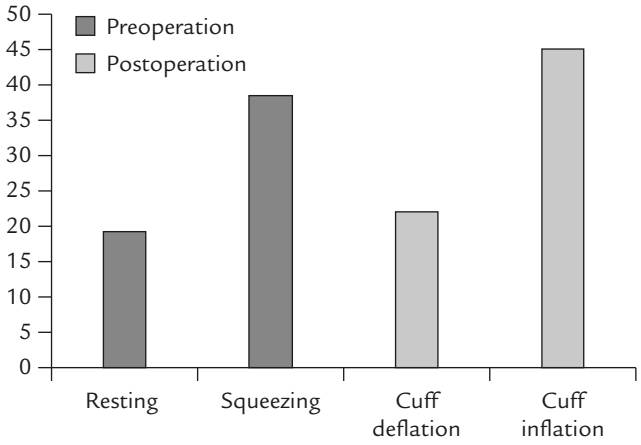

Figure 5. Changes in anal pressure (mmHg) before and after artificial anal sphincter implantation.

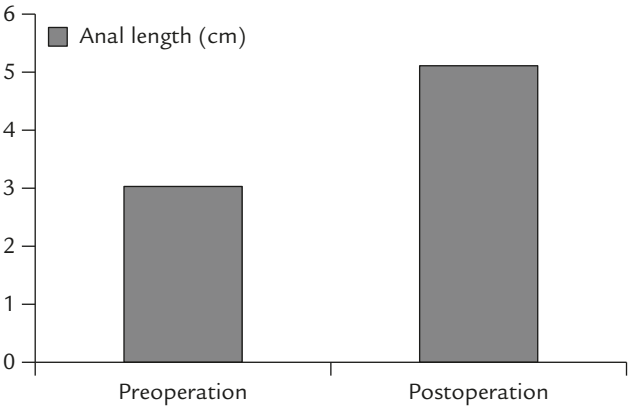

Figure 6. Changes in high pressure zone or anal length before and after artificial anal sphincter implantation.

Table 6. Continence grading scale (CGS)[14,16,18,19]

Study	Continence grading scale mean (range)	
	Before implantation	After implantation
Valzey et al[14]*	96.2 (70–108)	19.4 (0–61)
Lehur et al[16]*	106 (13)†	25 (25)†
O'Brien et al[18]‡	19 (18–20)	3 (0–6)
Ortiz et al[19]‡	18 (14–20)	4 (0–14)
Present series‡	13 (12–14)	5.5 (0–9)

*American Medical System Incontinence Score; †mean (SD); ‡Cleveland Clinic Florida Scale.

was the inability to properly deflate the cuff. These symptoms improved after re-education on the proper usage of the device. This aspect of postoperative care should not be overlooked. Romano et al[20] showed that regular training contributed significantly to overcoming this problem in patients. Another possible cause of obstructed defecation is a cuff selection that is too wide or overly inflated, thereby making it stiff. Altomare et al[12] reported a greater difficulty in defecation in patients when a 2.9-cm cuff (standard) was implanted compared to a 2.0-cm cuff (narrow). This potentially explains the lower incidence of this symptom in our series.

The baseline mean preoperative resting pressure was comparable to other reports (19 mmHg in our series *vs.* 16–45 mmHg in other studies; Table 7[3,7,12,14,15,19–22]). Following implantation, their resting pressure when the cuff was inflated rose appropriately (45 mmHg in our series *vs.* 54–85 mmHg in other studies). With deflation, their pressure subsequently decreased to a mean resting pressure of 21 mmHg (range: 32–37 mmHg in previous studies), allowing for defecation. Whilst most reports showed no difference in the mean anal length or high pressure zone, we found that this was increased in our patients (from 3 cm to 5 cm). This can be attributed to the predominantly male patients in our series.

We are aware of the inevitable limitations of this study. Firstly, the small number of patients in our series prevents

Table 7. Manometric results in published literature[3,7,12,14,15,19–22]

Study	Preoperative resting pressure (mmHg)	Preoperative squeezing pressure (mmHg)	Cuff deflated (mmHg)	Cuff inflated (mmHg)	Preoperative anal length (cm)	Postoperative anal length (cm)
Wong et al[3]	16	NA	NA	68	NA	NA
Devesa et al[15]	32	61	NA	55	NA	NA
Lahur et al[21]	41	72	NA	NA	1.9	2.1
Altomare et al[12]	27	42	32	67	Not different	Not different
Vaizey et al[14]	42* (54.7)	NA	NA	85* (110)	NA	NA
Savoye et al[7]	39* (51)	NA	37* (48)	83* (108)	NA	NA
Romano et al[20]	NA	NA	32	62	NA	NA
Casal et al[22]	45	75	NA	81	2.7	2.8
Ortiz et al[19]	35	NA	NA	54	NA	NA
Present series	19	38	21	45	3	5

*Values converted from cmH_2O to mmHg, values in parentheses expressed in mmH_2O. NA = not available.

us from making any statistically significant conclusions. Secondly, the main outcome measurements after device implantation which included CGS score and FIQL scores were not performed at the same points in time before and after implantation, which may result in a lead time bias. Thirdly, the retrospective nature of this study implies that the management protocols were varied for each surgeon. Finally, the FIQL questionnaire which has been validated in the western population may not be appropriate in an Asian population due to the difference in life style and social values. In addition, some of the questions may be misinterpreted during translation into the various dialects. Nevertheless, this study does demonstrate improvements in functional outcomes, quality of life and manometric results with an acceptable of incidence of morbidity and is the first reported series confined specifically to an Asian population.

Conclusions

The Acticon Neosphincter is a suitable option for the treatment of intractable faecal incontinence in Asian patients. Infection remains the major impediment to good outcomes.

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