Long-Term Outcomes of Artificial Bowel Sphincter for Fecal Incontinence: A Systematic Review and Meta-Analysis

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Fecal incontinence (FI) is a symptom with considerable adverse impact on quality of life. It is estimated that FI affects up to 18% of the population.[1] The treatment of medically refractory severe FI remains challenging. Christiansen and Lorentzen[2] first reported successful perianal implantation of an artificial urinary sphincter (AMS 800; American Medical Systems) for FI in 1987. Subsequently, Lehur and colleagues[3] started using Acticon Neosphincter (American Medical System), designed specifically for FI in 1996. Since that time, the artificial bowel sphincter (ABS) has produced good results.[4] However, even with improved experience, the incidence of surgical revision and explantation remains high.[5] Consequently, between technical challenges and high rates of additional surgery for complications, the device never became widely accepted.[5,6] Possible indications include end-stage severe FI associated with extensive anal sphincter loss or congenital anorectal malformation, where the only other option is a stoma.[7]

Despite these problems, many authors reported considerable improvement in continence and quality of life. Recently, Wexner and colleagues[8] found that the cumulative risk of device explant increases with time, but less dramatically in the longer follow-up. In addition, even after device explant due to infection, reimplantation has been done without difficulty.[9] To assess the effectiveness of this device, we sought to examine the proportion of patients who have a functional device as well as the functional outcomes in this population during long-term follow-up. Most studies have had small number of patients, different lengths of follow-up, and often <5 years of follow-up.

In this systematic review, we considered the changes in device-related outcomes and functional outcomes according to follow-up length and, finally, investigated long-term outcomes of ABS.

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METHODS

Literature search strategy

The systematic review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Statement Guidelines, provided in 2009 by an international study group. The database MEDLINE, Web of Science, and Cochrane Library were searched from January 1987 to August 2012. Keywords used were *artificial anal sphincter* OR *artificial bowel sphincter*, *prosthetic anal sphincter* OR *prosthetic bowel sphincter* (*fecal* OR *faecal* OR *anal incontinence*) AND *surgical treatment*. Reference lists of identified articles were screened for additional publications of interest. Two reviewers (KH and YC) independently reviewed all records by title and abstract followed by full-text articles for those meeting the screening criteria.

Inclusion criteria

Reports of randomized trials, cohort studies, case-control studies, and case series were included. The review was restricted to articles published in the English language. Minimum mean or median follow-up of 1 year from the time of ABS surgery were eligible for review. When the same cohort was enrolled in different studies, only the most recent publication with long-term follow-up was included. Case reports with <5 patients enrolled were excluded. The articles that just enrolled selective patients with well-functioning devices were excluded to avoid selection bias and confounding toward better outcomes.

All articles selected for full-text review were distributed to 2 reviewers (KH and YC), who independently decided on inclusion and exclusion and independently abstracted the study data. Any discrepancies in agreement were resolved by consensus. The flow chart of this selection process has been summarized in Figure 1. The primary outcomes were device related: surgical

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Abbreviations and Acronyms

ABS = artificial bowel sphincter
CC-FIS = Cleveland Clinic Fecal Incontinence Score
FI = fecal incontinence
QOL = quality of life
QS = quality score

revision, definitive explants, and functioning device at last follow-up. Device-related outcomes were calculated based on an intent-to-treat basis (we divided each event by the number of initial enrolled patients, excluding patients lost to follow-up). If articles did not describe the number of patients lost to follow-up, initially enrolled patients were considered as the denominator. Secondary outcomes were functional, including evacuatory disorder, manometric results, continence, and quality of life (QOL).

Quality assessment

The appraisal of study quality was undertaken using a checklist that was based on the Newcastle-Ottawa Scale,[10] including adequate case definition using a physical examination or preoperative physiologic test (eg, endoanal sonography or manometry); clear patient selection, if possible, consecutive or obviously representative case series; control group for comparison; validated subjective outcomes measures about FI state or QOL; adequate postoperative outcomes, including device-related adverse events, and follow-up duration >75% of initial enrolled patients. A quality of score (QS) was determined for each study, with a maximum score of 5 indicating the highest quality of study design.

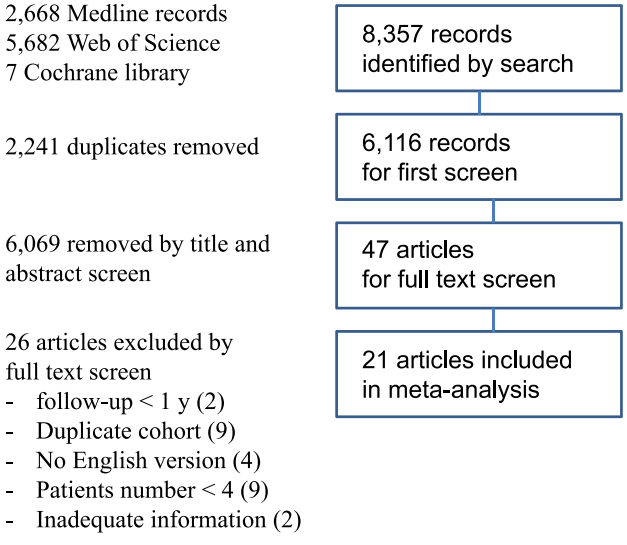

Figure 1. Systematic review flow diagram.

Statistical analysis

A single weight-adjusted mean or proportion for each variable or result was computed for each study. To derive pooled estimates of proportions with 95% CI for the outcomes explored, random effect model was used. Data pooling and statistical analysis comparing outcomes for 3 groups with different follow-up lengths was performed with Comprehensive Meta-Analysis Version 2 (Biostat). A p value <0.05 was considered as statistically significant.

RESULTS

Study selection and characteristics

Forty-seven full-text articles were retrieved from the screening of 6,116 records, which included 23 study populations derived from 21 articles (Fig. 1). Specifically, there was 1 case-control study[11] and 20 case series,[4,8,9,12-28] with a total of 541 patients identified. The articles by Michot and colleagues[18] and Parker and colleagues[19] included 2 study populations with different study periods in the same article. There were 4 different types of device models. The AMS 800 was used in 4 studies,[12,13,18,19] the modified AMS 800 was used in 1 study,[13] and Acticon Neosphincter was used in 18 studies,[4,8,9,11,14-22,24-28] all of which were implanted in the perianal area. There was one study with transabdominal implantation of artificial sphincter by Biosil[23] (Table 1). According to follow-up length, we divided the 23 study populations into 3 groups; group I: 1 to 2.9 years vs group II: 3 to 4.9 years vs group III: ≥5 years. There were 12 study populations[4,12,14-18,20,22,24,26,28] in group I, 6[8,11,19,21,23,27] in group II, and 5[9,13,18,19,25] in group III. Some studies had overlapped patients partially with others. Eight patients were overlapped between the study by Lehur and colleagues[12] and the study by Michot and colleagues,[18] 26 patients between the study by Wong and colleagues[4] and the study by Parker and colleagues,[19] and 24 patients between the study by Lehur and colleagues[14] and the study by Wong and colleagues.[9]

In all studies, the ABS was implanted in patients with severe end-stage FI. The most common cause was sphincter destruction, usually after failed sphincter repair (Table 2). Romano and colleagues[20] included only perineal colostomy as an indication of ABS in their study. Obvious indications for the ABS are complete absence or substantial destruction of the sphincter muscle, congenital malformation, such as imperforate anus or spina bifida, or perianal colostomy after abdominoperineal resection.[18,29] In this meta-analysis, 26% of ABS implantations were for congenital malformation or perineal colostomy. If we consider that some patients with

Table 1. Included Study Characteristics

First author	Year	Period of surgery	Device model	Study design	Length of follow-up, mo (range)	Initial no.	Lost to follow-up, n	Total no. of surgical revisions	Definite explant of device	Functioning device	QS
Lehur[12]*	1996	1989–1995	AMS 800	Retrospective review	Median 20 (4–60)	13	NA	6	3	10	3
Christiansen[13]	1999	1987–1993	AMS 800 mAMS 800	Retrospective review	Median 84 (60–120)	6 11	0	13	7	8	3
Lehur[14]†	2000	1996–2000	Acticon	Prospective	Median 20 (6–35)	24	0	10	4	20	4
Savoye[15]	2000	1996–1998	Acticon	Retrospective review	Mean 16 (4–28)	12	0	NA	0	12	3
Devesa[16]	2002	1996–2000	Acticon	Prospective	Mean 27 (7–55)	53	1	NA	10	26 in 43‡	4
Ortiz[17]	2002	1996–2000	Acticon	Retrospective review	Mean 28 (6–48)	22	0	14	7	15	4
Wong[4]§	2002	1997–2001	Acticon	Prospective	Median 12	112	3	73	34	76	4
Michot,[18]* group 1	2003	1993–1996	AMS 800	Retrospective review	Mean >60	12	0	7	6	5	1
Michot,[18]* group 2	2003	1996–2001	Acticon	Retrospective review	Mean 34 (7–60)	25	0	15	3	18 in 19‖	2
Ortiz[11]	2003	1996–1998	Acticon	Case control	Median 44	8	0	6	3	5	4
Parker,[19]§ group 1	2003	1989–1992	AMS 800	Retrospective review	Mean 9 (29–13)	10	0	12	4	6	1
Parker,[19]§ group 2		1997–2001	Acticon	Prospective	Mean 39 (12–60)	37	3	NA	18	17	4
Romano[20]	2003	1999–2001	Acticon	Retrospective review	(6–28)	8	0	NA	0	8	3
Altomare[21]	2004	NA	Acticon	Retrospective review	Median 50	28	3	18	9	6 in 14¶	3
Casal[28]	2004	1998–2002	Acticon	Prospective	Mean 29	10	NA	4	1	9	4
La Torre[22]	2004	1999–2002	Acticon	Retrospective review	Mean 26 (3–40)	8	2	4	2	6	3
Finlay[23]	2004	NA	Biosil#	Retrospective review	Median 59 (30–72)	12	0	9	3	9	3
Melenhorst[24]	2008	1997–2006	Acticon	Prospective	Mean 17 (1–106)	34	1	NA	7	26	4
Ruiz Carmona[25]	2009	1996–2002	Acticon	Retrospective review	Mean 68 (3–133)	17	NA	19	7	9	4
Wexner[8]	2009	1998–2007	Acticon	Retrospective review	Mean 39 (3–108)	47	0	40	14	30	2
Chittawatanarat[26]	2010	2004–2007	Acticon	Retrospective review	Mean 22 (4–36)	6	0	2	2	4	3

(Continued)

Table 1. Continued

First author	Year	Period of surgery	Device model	Study design	Length of follow-up, mo (range)	Initial no.	Lost to follow-up, n	Total no. of surgical revisions	Definite explant of device	Functioning device	QS
Michot[27]	2010	2003–2007	Acticon**	Retrospective review	Median 41 (18–75)	32	0	11	9	23	4
Wong[9]*	2011	1996–2010	Acticon	Retrospective review	Mean 64 (2–169)	52	9	43	14	35	4

*Overlap of 8 patients between 2 studies.
†Overlap of 24 patients between 2 studies.
‡In 5, the cuff was always activated because the patients could evacuate without difficulty, in 12, the cuff was nearly always deactivated per the patients' own decision.
§Overlap of 26 patients between 2 studies.
||In 1 patient, the cuff was deactivated with a defunctioning stoma.
¶Eight of the 14 patients no longer activated the pump because of obstructed defecation (n = 7) or anal pain (n = 1).
#This device was applied in anorectal junction via transabdominal approach.
**Device was applied in perianal area via transvaginal approach and other devices were applied in perianal area via perineal approach.
mAMS 800, modified AMS 800; NA, not available; QS, modified Newcastle-Ottawa Scale.

extensive sphincter damage were enrolled because of sphincter destruction, we notice that approximately one third of patients had no other viable alternative to ABS.

Device-related outcomes

There was no mortality cases related to the ABS. One study[23] included a major complication of a total colectomy due to pseudomembranous colitis after implantation. Most other complications were treated with observation; antibiotics; or device revision, replacement, or explantation.

Surgical revision was defined as the total number of device revisions, including explant and reimplantation. When explant and reimplantation were done simultaneously, the number of revisions was considered one. The surgical revision rate was evaluated in 8 study populations[4,12,14,17,18,22,26,28] of group I (n = 218), 5[8,11,21,23,27] of group II (n = 124), and 4[9,13,19,25] of group III (n = 87). The pooled rate of surgical revision was 49% (95% CI, 42–55) in group I, 69% (95% CI, 45–86) in group II, and 94% (95% CI, 74–99) in group III, respectively (group I vs group II; $p = 0.03$, group II vs group III; $p < 0.001$, group I vs group III; $p < 0.001$) (Fig. 2).

The indications for surgical revision were evaluated in 14 studies.[4,9,11-14,17-19,22,23,25,26,28] The most common reason for surgical revision was device malfunction, such as cuff rupture; balloon and pump leak, and cuff unbuttoning (Table 3). Repeated inflation and deflation usually makes the cuff fatigue and eventually leak or rupture.

A definite explant was defined as the number of patients who had undergone permanent removal of the device. In addition, patients who had undergone explant but were awaiting reimplantation at last follow-up in each study were also considered as permanent explants. All 23 study populations were available at this result. The pooled rate of definite explant was 24% (95% CI, 19–29%) in group I, 36% (95% CI, 27–45%) in group II, and 39% (95% CI, 29–49%) in group III, respectively (Fig. 2). The most common reasons were device infection and erosion; pooled rates were 56% (95% CI, 42–69%) and 37% (95% CI, 26–51%), respectively. However, in many cases, it could not be determined whether the infection or the erosion occurred first. Device malfunction did not appear to be a major cause of definite failure; pooled rate was 19% (95% CI, 13–28%). To lower the infection rate, meticulous surgical technique, asepsis, and perioperative care have been emphasized.[13,14,16,25,27] Although Finlay and colleagues[23] implanted the cuff above the pelvic floor, the explant rate due to infection was 25%. Michot and colleagues[27] tried the transvaginal approach in patients with destroyed or severely scarred anterior perineum, as these patients have a high risk of

Table 2. Indication of Artificial Bowel Sphincter Implantation

Indication	Range of proportions reported by primary studies, %	Pooled proportion, %	95% CI, %
Sphincter destruction	25–91	57	48–65
Neurogenic disorder	0–59	21	15–28
Congenital malformation	0–51	21	17–24
Idiopathic	0–50	7	3–15
Perineal colostomy	0–100	5	3–8

perineal erosion and are not candidates for ABS. Other reasons for definite explant were fecal impaction in 1 patient[13] and lack of improvement in 1 patient.[19]

A functional device at last follow-up was defined as not just the number of patients with implanted ABS, but the number of patients actively using their device. All 23 study populations were available at this result. The pooled rate of retaining a functional device was 69% (95% CI, 53–82%) in group I, 57% (95% CI, 42–71%) in group II, and 59% (95% CI, 42–81%), respectively (Fig. 2).

Functional outcomes

Evacuatory difficulty

Thirteen study populations[11-15,17-19,21,22,26-28] reported various degrees of evacuatory difficulty among patients with an implanted device at last follow-up. The pooled rate (95% CI) of evacuatory difficulty was 34% (95% CI, 27–42%). Most evacuatory difficulty was relieved by laxatives, enemas, or treatment deactivation. However, severe evacuatory difficulty was resolved by anesthesia, surgical revision, or admission for fecal disimpaction. The portion of severe evacuatory difficulty after activation was available in only 5 study populations,[4,9,16,24,25] of which the pooled rate was 8% (95% CI, 4–15%). Because the severity is the subjective concept of the authors or patients, the interpretation requires caution. There were some proposed causes for this problem. It might be due to pre-existing evacuation problems that went unnoticed at the time of surgery because of long-standing incontinence.[13,18,30] Michot and colleagues[18] recommended preoperative assessment by defecography and colonic transit time to correct complete rectal prolapse, internal rectal procidentia, or anterior rectocele before ABS implantation. A short cuff, device malfunction, or short opening time of the sphincter might be a cause of evacuatory difficulty.[4,15,16,19,25] The pooled rate of surgical revision for evacuatory difficulty was as low as 8%. Wong and colleagues[9] advised patients to use laxatives or enemas as needed.

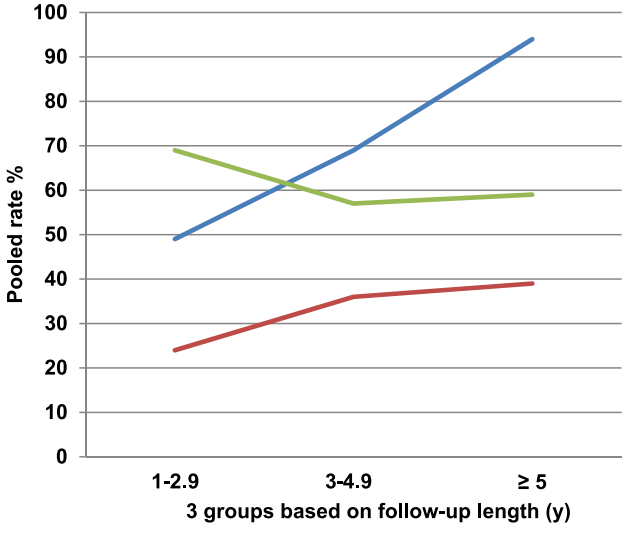

Figure 2. Device-related outcomes according to length of follow-up. Blue line, surgical revision; red line, definite explant; green line, functional device.

Anal manometry

Twelve study populations compared resting anal pressure before and after implantation with the ABS cuff opened and closed.[4,9,11,14-17,19,24-26,28] A substantial increase in anal resting pressure occurred after implantation, except in one study.[24] Five study populations compared squeeze anal pressure before and after implantation with the ABS cuff closed.[16,19,24,27,28] In 3 study populations,[16,24,27] there was a considerable increase in anal squeeze pressure after implantation, otherwise, in 2 study populations,[19,28] there was no difference in anal squeeze pressure between preoperative and postoperative values. Many studies did not report the time interval at which the manometry was performed.[11,14-18,20,22,26,28] In four study populations[4,9,19,25] the postoperative resting pressures were assessed at multiple occasions at different lengths of follow-up. In all 4 studies, preoperative resting pressure was substantially different with postoperative resting pressure at all points. However, there was no difference in resting pressure between 6 and 12 months of follow-up. Specifically, 2 high-quality studies[9,25] (QS = 4) with >5 years of mean follow-up showed no differences in resting pressure between postoperative activation and last follow-up. This finding indicates that manometric pressure seems to be well preserved over time.

Table 3. Indication of Surgical Revision

Indication (14 of study population*)	Range of proportions reported by primary studies, %	Pooled proportion, %	95% CI, %
Device malfunction	0–69	36	23–52
Erosion	0–50	29	19–40
Infection	0–55	28	19–38
Reimplantation	0–40	12	8–18
Pain	0–25	10	6–15
Migration	0–17	8	5–12
Defecation difficulty	0–17	6	3–11
No improvement of incontinence	0–17	5	3–9

*Fourteen of the studies.[4,11-14,17-19,22,23,25,27,29,30]

Fecal incontinence

Twelve study populations[12-19,21,25,27,28] were available for continence to solid, liquid, and gas. Even those patients who had a functional device at last follow-up experienced decreased continence that deteriorated with increasing time (Table 4).

Three different types of validated FI scoring method were used: the Williams, the American Medical System, and the Cleveland Clinic Fecal Incontinence Score (CC-FIS).[31] Fifteen study populations presented the FI score before and after implantation.[4,9,11,13,14,16,17,19,21,22,24-28] Although most studies used these scoring methods to provide preoperative scores on nearly all enrolled patients, post-implantation scores were given only for those with a functional device at the end of follow-up. Only one study reported the continence state of patients in whom the device was explanted.[9] Wong and colleagues[9] showed there was no statistical difference in CC-FIS before and after operation in patients who had their devices explanted.

Two studies used the Williams score, which measures continence on a scale of 1 to 5, where 1 presents complete continence and 5 complete incontinence.[13,24] Each study showed the 50%[13] and 56%[24] of substantial improvement in continence after implantation. Six studies used the AMS score, which measures continence on a scale of 0 to 120, where 0 presents complete continence and 120 complete incontinence.[4,14,19,21,22,28] Preoperative American Medical System score ranged from 94 to 106 and postoperative American Medical System score ranged from 5 to 69; difference was statistically significant in all 6 studies. The

Table 4. Continence State of Patients with Functional Device at Last Follow-Up

Reference based on follow-up duration	Patients analyzed, n	Solid continence, n	Liquid continence, n	Gas continence, n
1–2.9 y				
Lehur et al, 1996[12]	10	10	9	5
Lehur et al, 2000[14]	20	19	19	6
Savoye et al, 2000[15]	12	12	8	7
Devesa et al, 2002[16]	43	43	17 in 26	29
Ortiz et al, 2002[17]	15	14	9	4
Michot et al, 2003, group 2[18]	19	19	15	12
Casal et al, 2004[28]	9	9	5	2
Pooled proportion, % (95% CI)		96 (90–98)	71 (59–81)	47 (33–62)
3–4.9 y				
Altomare et al, 2004[21]	14	NA	NA	8
Michot et al, 2010[27]	23	23	19	11
Pooled proportion, % (95% CI)		98 (74–100)	83 (62–93)	51 (36–67)
≥5 y				
Christiansen et al, 1999[13]	8	7	4	1
Parker et al, 2003, group 1[19]	10	4	4	1
Ruiz Carmona, et al, 2009[25]	9	6	4	1
Pooled proportion, % (95% CI)		63 (34–85)	45 (27–63)	11 (4–29)

NA, not available.

pooled improvement rate after implantation was 63% (95% CI, 45−77%) in these 6 studies using American Medical Systems score. Seven studies used CC-FIS, which measures continence on a scale of 0 to 20, where 0 presents complete continence and 20 complete incontinence.[9,11,16,17,25-27] Preoperative CC-FIS ranged from 13 to 18.5 and postoperative CC-FIS ranged from 4 to 8; differences were statistically significant in all 7 studies. The pooled improvement rate after implantation was 65% (95% CI, 56−73%) in 7 studies using CC-FIS. Because studies using CC-FIS were distributed relative evenly through the length of follow-up, we compared the pooled improvement rate before and after implantation between 3 groups. The pooled improvement rate was 75% (95% CI, 62−84%) in group I,[16,17,26] 60% (95% CI, 42−75%) in group II,[11,27] and 55% (95% CI, 40−69%) in group III.[9,25] The pooled improvement rate showed statistical difference between group I (n = 62 patients) and group III (n = 44 patients) (p = 0.03). Overall, continence seems to decrease with time.

Quality of life

Nine study populations evaluated the QOL score before and after implantation, using 4 different methods of assessment.[1-3,5,13,16-18,21] All study populations revealed significant improvements in QOL after implantation and specifically at long-term follow-up, 2 studies (QS = 4) revealed considerable improvement of QOL after implantation.[9,25] However, in most studies, post-implantation scores were given only for patients with a functional device at last follow-up. Only one study reported the QOL score of patients in whom the device was explanted.[9] Wong and colleagues[9] (QS = 4) showed there was no improvement of QOL before or after explantation.

DISCUSSION

Since the commercialization of sacral nerve stimulation, ABS implantation has been limited. In patients with no sphincter defect or with a defect of <180 degrees, sacral nerve stimulation is generally the proposed surgical treatment.[32] However, patients with extensive sphincter destruction, congenital malformation, or perineal colostomy might not be candidates for sacral nerve stimulation.

The major cause of definitive explant is infection. Unfortunately, neither the rate of infection nor the rate of definite explant has decreased, perhaps due to the innate problem of implanting prosthetic material in the anorectal region. Although novel innovations have been attempted,[23,27] meticulous surgical technique, asepsis, and appropriate perioperative care seem to be the best way to minimize these problems.[23,27] The most common cause of surgical revision was device malfunction, so technical improvements are required. Although mild evacuatory difficulty was common, it was severe in only 8% (pooled rate). Appropriate preoperative assessment for outlet obstruction and close postoperative surveillance for constipation with liberal use of laxatives or enemas seems advisable. Continence, as measured by CC-FIS in patients with a functioning device at last follow-up, seems to decrease with time. Despite this decrease, QOL of patients remained high.

The authors divided the collected studies into 3 groups according to the length of follow-up. Because the primary study outcomes were device related, this division seems to be appropriate. However, this article has several limitations. The most appropriate methodology for determining the "rate" of functioning ABS at any given time interval after implantation is to perform time-to-event analysis. To enable this calculation, the authors needed the raw data, including censored and uncensored follow-up, from each source article to construct their own Kaplan-Meier curve to determine rates of longevity of ABS. However, given that the vast majority of the source studies did not contain such data, these calculations could not be performed. Each study population was heterogeneous and each patient had different follow-up length, even within same group. All studies reported the outcomes only on responders, which cannot be generalized to all patients with an ABS. More satisfied than unsatisfied patients are likely to respond to surveys and questionnaires, which could lead to overoptimistic results.[33] In addition, in all but one study, the postoperative FI and QOL scores were measured only for patients with a functional device at last follow-up.[9]

CONCLUSIONS

This systematic review found that the need for surgical revision increases as continence decreases with time. Although functioning devices stabilize to a pooled rate of 59% after >5 years of follow-up, continence as measured by the CC-FIS in patients with a functional device decreases with time. Interestingly, despite this decrease, the QOL of patients remained high. Although evacuatory difficulty was common, it was severe in only 8% of patients. Accordingly, preoperative assessment for outlet obstruction and postoperative surveillance with instructions to liberally use laxatives or enemas seems advisable. Meticulous aseptic techniques and device refinements are both highly desirable to help improve these outcomes.

Author Contributions

Study conception and design: Hong, Dasilva, Wexner
Acquisition of data: Hong, Chong

Analysis and interpretation of data: Hong, Chong
Drafting of manuscript: Hong, Kalaskar, Wexner
Critical revision: Hong, Dasilva, Kalaskar, Wexner

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