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REVIEW

Current status: new technologies for the treatment of patients with fecal incontinence

Andreas M. Kaiser · Guy R. Orangio · Massarat Zutshi · Suraj Alva · Tracy L. Hull · Peter W. Marcello · David A. Margolin · Janice F. Rafferty · W. Donald Buie · Steven D. Wexner

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Abstract Fecal incontinence is a frequent and debilitating condition that may result from a multitude of different causes. Treatment is often challenging and needs to be individualized. During the last several years, new technologies have been developed, and others are emerging from clinical trials to commercialization. Although their specific roles in the management of fecal incontinence have not yet been completely defined, surgeons have access to them and patients may request them. The purpose of this project is to put into perspective, for both the patient and the practitioner, the relative positions of new and emerging technologies in order to propose a treatment algorithm.

Abbreviations

ABS	Artificial bowel sphincter
CCFIS	Cleveland Clinic Fecal Incontinence Score
FDA	Food and Drug Administration (USA)
FI	Fecal incontinence
MACE	Malone antegrade colonic enema
PNS	Pudendal nerve stimulation
PTNS	Percutaneous tibial nerve stimulation
SNS	Sacral nerve stimulation
PRT	Prospective randomized trial
PT	Prospective trial/study
SR	Systemic review
RS	Retrospective series
CR	Case report

Fecal incontinence is a frequent and debilitating condition that may result from a multitude of different causes. Treatment is often challenging and needs to be individualized [1, 2]. During the last several years, new technologies have been developed, and others are emerging from clinical trials to commercialization. Although their specific roles in the management of fecal incontinence have not yet been completely defined, surgeons have access to them and patients may request them. The purpose of this project is to put into perspective, for both the patient and the

Members of the ASCRS Task Force "New Technologies for the Treatment of Patients with Fecal Incontinence."

A. M. Kaiser (✉)
Department of Colorectal Surgery, Keck School of Medicine, University of Southern California, 1441 Eastlake Avenue, Suite 7418, Los Angeles, CA 90033, USA
e-mail: akaiser@usc.edu

G. R. Orangio
Louisiana State University Health Science Center, New Orleans, LA, USA

M. Zutshi · T. L. Hull
Cleveland Clinic Foundation, Cleveland, OH, USA

S. Alva
Robert Wood Johnson Medical School, New Brunswick, NJ, USA

P. W. Marcello
Lahey Clinic, Burlington, MA, USA

D. A. Margolin
Ochsner Clinic, New Orleans, LA, USA

J. F. Rafferty
University of Cincinnati, Cincinnati, OH, USA

W. D. Buie
University of Calgary, Calgary, AB, Canada

S. D. Wexner
Cleveland Clinic Florida, Weston, FL, USA

practitioner, the relative positions of new and emerging technologies in order to proposes a treatment algorithm.

In order to keep pace with this rapidly advancing technology, the Executive Council of the American Society of Colon and Rectal Surgeons (ASCRS) convened a task force composed of Society chairpersons and key members of the Standards of Practice, New Technology, and Socioeconomic Committees. This systematic review sought to assess the currently available evidence for various new techniques in order to provide a rational basis for practitioners, healthcare workers, and patients who desire information about the value and perspective of these new treatment tools. This is particularly important given the fact that many of these technologies are approved by the US FDA, and in some cases are already included in the physician fee schedule. Ultimately, clinical efficacy may need to be determined by actual clinical experience due to limits in research funding. For that purpose, the medical literature was thoroughly searched, the articles were analyzed, and the recommendations and level of evidence in regards to benefits and risks were determined according to the GRADE system. The severity of fecal incontinence was evaluated in most of the literature utilizing the Cleveland Clinic Fecal Incontinence Score (CCFIS) (see Table 14 in Appendix 1) [127]. It should be recognized that any particular intervention may only represent one element in a combination of surgical and non-surgical therapies, and that in light of all the circumstances presented by the individual patient, the physician must make the ultimate judgment regarding the appropriateness of any specific procedure. The current evaluation is based on thorough review of both prospective trials and smaller case series. When the literature was lacking high-quality evidence for a rigid scientific review, the ultimate recommendations of the expert panel were reached in group consensus. Furthermore, where insufficient data for the treatment of fecal incontinence were found, predicate use of the techniques for the treatment of other problems was included.

The expert panel's recommendations are not meant to be either an endorsement for or a rejection of any single drug, device, method, or manufacturer. Generic names have been used throughout the document, even in therapeutic fields in which only a single product, procedure, or manufacturer exists.

Furthermore, one should note that the more traditional treatments such as physical therapy and pelvic floor rehabilitation, sphincteroplasty, or creation of a colostomy are not the focus of this review but may be appropriate choices for respective patients [3]. These methods were assessed by the ASCRS in the practice parameter 'Management of fecal incontinence', of which the last version from 2007 is currently being updated for publication in 2014 [4].

For the purpose of this review on the current status of new technologies for fecal incontinence, treatment options and techniques were categorized with respect to the goal of the intervention (Table 1). The order of discussion is reflective of that structure and not based on preference for any method.

Table 1 Technologies addressed in this review

Goal	Reviewed methods	Literature overview
Category I		
Passive increase of outlet resistance	Injection of bulking agents	
	Submucosal injection of anal canal with non-animal dextranomer microspheres in stabilized sodium hyaluronate	Table 2
	Submucosal injection of anal canal with traditional injectable bulking agents (carbon/teflon/silicon beads, collagen, fat)	Table 3
	Induction of scarring and remodeling	
	Radiofrequency energy delivery	Table 4
Category II		
Stimulation/ improvement of neuromuscular function	Sacral nerve stimulation	Table 5
	Posterior tibial nerve stimulation	Table 6
	Pudendal nerve stimulation	Table 7
	Pudendal nerve decompression	Table 8
	Femoral nerve transfer	–
Category III		
Replacement of sphincter function	Artificial bowel sphincter	Table 9
	Magnetic ring	Table 10
	Perineal puborectalis sling	Table 11
Category IV		
Reduction of stool load	Percutaneous trapdoor button for malone antegrade colonic enema	Table 12

Category I: passive increase of outlet resistance

Injection of bulking agents

Method: Submucosal injection of anal canal with non-animal dextranomer microspheres in stabilized sodium hyaluronate

FDA approval 2011.

Goal of the procedure Injection of biocompatible bulking agents into the submucosa of the anal canal in order to expand the tissue and improve the seal of the anal canal and hence prevent passive fecal incontinence.

Table 2 Injection of silicon dextranomer

Author	Publication	Year	*n*	Study design	FI severity score[a] (range)		F/U (months)	Functional success rate (%)		Failures (*nl/N*)	Complications (%)
					Before	After		Complete continence	>50 % improvement		
Danielson et al. [5]	Dis Colon Rectum	2009	34	PT	14 (6–18)	12 (11–16)	12	0	56	14/34	
Dodi et al. [6]	Gastroenterol Res Pract	2010	86	PT	13.5[a]	8.7	12	NA	64	NA	Fever (7), abscess (3.4)
Graf et al. [7]	Lancet	2011	278	PRT	14.3	10.9	12	0	57.4	119/278	2
Schwandner et al. [8]	Surg Innov	2011	21	PT	16.8	12.3	20	0	61.2	8/21	

FI fecal incontinence, *F/U* follow-up, *PT* prospective trial/study, *PRT* prospective randomized trial, *NA* not available

[a] Cleveland Clinic fecal incontinence score 0–20 unless stated otherwise

Description of technique The treatment is performed through an anoscope. Four 1-ml injections of gel with dextranomer microspheres/stabilized sodium hyaluronate are administered from 5 to 10 mm proximal to the dentate line in the submucosal layer, at the 3, 6, 9, and 12 o'clock positions. The needle is retained in situ for 10 s to prevent leakage of the gel.

Setting Office or outpatient facility. Neither sedation nor local anesthesia is needed. Perioperative antibiotics are not routinely recommended, but potentially justified on a case-by-case basis.

Summary of published evidence (Table 2) There are four prospective trials (only one double-blinded) with a total of more than 400 patients who showed a response rate of 56–61 % within 12–20 months of follow-up [5–8]. There was improvement in fecal incontinence scores on the first injection but a high percentage of patients required multiple injections to achieve 'improvement' in the number of episodes of fecal incontinence; none of the studies reported 100 % improvement. The largest series was a prospective, randomized, double-blinded and sham-controlled multicenter trial in Europe and the US [7]. Overall, 278 incontinence patients aged 18–75 years were screened for inclusion, of which 206 were enrolled, with 136 versus 70 patients randomized to receive dextranomer or sham injections, respectively. The response was defined as a reduction in the number of weekly incontinence episodes by 50 % or more. Dextranomer-injected patients had a 52 % reduction compared with a 31 % reduction in the sham treatment group. The procedure overall was reported to be safe, with only a small rate of complications (2 % of the patients), but pain at the injection site in 26 % of patients after the first injection, and 56 % after the second injection. Only two serious complications occurred (prostatic and rectal abscess).

Indications for this procedure

- Minor to moderate fecal incontinence (CCFIS 1–14)
- Failed conservative treatment (dietary, fiber supplements, antidiarrheal medications, and sphincter exercises)

Contraindications for this procedure

- Total internal and external sphincter defect (i.e. seen at all levels of the anal canal)
- Pregnancy
- Hemorrhoid or mucosal prolapse
- Inflammatory bowel disease
- Anorectal surgery within the past year
- Anticoagulant medication/uncorrected bleeding diathesis
- Anorectal sepsis
- Immunocompromised patient

Complications

- General: Temporary pain (26 % after the first injection, 56 % after the second injection), bleeding, infection

Table 3 Injection of traditional injectables

Author	Publication	Year	*n*	Bulking Agent	Study design	FI severity score[a] (range)		F/U (months)	Functional success rate (%)		Failures (*n*/*N*) (%)	Complications (*n*/*N*) (%)
						Before	After		Complete continence	>50 % improvement		
Kumar et al. [9]	Br J Surg	1998	17	Gax-Collagen	PT	NA	NA	6	NA	NA	17	None
Davis et al. [10]	Aliment Pharmacol Ther	2003	18	Carbon-coated beads	PT	11.89	8.07	12	NA	NA	11	Mild anal discomfort (11 %)
Tjandra et al. [11]	Dis Colon Rectum	2004	82	Injectable silicone biomaterial	PRT (A)	14.5	5	6	0	>50		Pain in both groups
					PRT (B)	(10–20) 14.5 (11–20)	(2–13) 8 (2–12)		0	>40		
Stojkovic et al. [12]	Br J Surg	2006	73	Collagen	PT	10	6	12	5	NA	37	
Chan and Tjandra [13]	Dis Colon Rectum	2006	7	Injectable silicone biomaterial	PT	12 (9–14)	2 (0–5)	14	NA	>50	NA	Pain
Altomare et al. [14]	Dis Colon Rectum	2008	33	Carbon-coated beads	PT	12	8[d]	20.8	0	33.3		Pain
Ganio et al. [15]	Tech Coloproctol	2008	10	Calcium hydroxylapatite (Coaptite)	PT	85.6[b]	28[d]	12	0	80	20	
Maeda et al. [16]	Colorectal Dis	2008	5	Bulkamid	PRT	15[c]	12	6	NA	NA		
			5	Crosslinked porcine collagen		16[c]	14		NA	NA		
de la Portilla et al. [17]	Colorectal Dis	2008	20	Injectable silicone biomaterial	PT	13.5	9.4	24	0	60		
Soerensen et al. [18]	Colorectal Dis	2008	35	Injectable silicone biomaterial	PRT	12.7	11	12.9	0	NA	27	NA
Aigner et al. [19]	Dis Colon Rectum	2009	11	Carbon beads	PT	12.27	4.91	24	0	NA		Pain
Bartlett and Ho [20]	Br J Surg	2009	74	Injectable silicone biomaterial	PT	10 (6.8–15)	1 (0–4.3)[d]	28	0	70	29.7	
Tjandra et al. [21]	Colorectal Dis	2009	20	Injectable silicone biomaterial	PRT	11.45	3.80	12	NA	90	NA	None
Beggs et al. [22]	Colorectal Dis	2010	23	Carbon-coated beads	PT	18.7	10.9	12	0	NA	26	Pain, abscess (8.6 %)
Maslekar et al. [23]	Dis Colon Rectum	2013	100	Crosslinked porcine collagen	RS	14	8	≥36	0	68	32	0 %

FI fecal incontinence, *F/U* follow-up, *PT* prospective trial/study, *PRT* prospective randomized trial, *RS* retrospective series, *NA* not available

[a] Cleveland Clinic Fecal Incontinence Score 0–20 unless stated otherwise

[b] Fecal Incontinence Severity Index

[c] St. Mark's score

[d] $p < 0.05$

Table 4 Radiofrequency energy delivery

Author	Publication	Year	*n*	Study design	FI severity score[a] (range or SD)		F/U (months)	Functional success rate (%)		Failures (*n*/*N*)	Complications (*n*/*N*)
					Before	After		Complete continence	>50 % improvement		
Takahashi et al. [24]	Dis Colon Rectum	2002	10	PT[b]	13.5 (11–16)	5 (4–7)	12	NA	80 (8/10)	NA (1/10)	5/10
Efron et al. [27]	Dis Colon Rectum	2003	50	PT	14.6 ± 3.4	11.1 ± 4.9	6	0	0 (0/50)	NA (>2/50)	26/50
Takahashi et al. [25]	Dis Colon Rectum	2003	10	PT[b]	13.8	7.3	24	NA	80 (8/10)	NA (1/10)	NA
Felt-Bersma et al. [28]	Eur J Gastroenterol Hepatol	2007	11	PT	18.8/24 (Vaizey score)	11.5/24 (Vaizey score)	12	NA	NA	NA (1/10)	5/11
Lefebure et al. [29]	Int J Colorect Dis	2008	15	PT	14.1 ± −4.5	12.3 ± 4.6	12	0	13 (2/15)	NA (4/15)	0
Takahashi-Monroy et al. [26]	Dis Colon Rectum	2008	19 (10 + 9)	PT[b]	14.4	8.3	60		84 (16/19)	NA	6/19
Kim et al. [30]	Am J Surg	2009	8	PT	35.1/61 (FISI)	25.6/61 (FISI)	6	0	37.5 (3/8)	5/8	7/8
Ruiz et al. [31]	Dis Colon Rectum	2010	16/24	PT	15.6 ± 3.2	12.9 ± 4.6	12	0	12.5 (2/16)	4/16	4/16
Abbas et al. [32]	Dis Colon Rectum	2012	27	RS	16 (8–20)	10.9	24	0	22	6/27	5/27

FI fecal incontinence, *F/U* follow-up, *PT* prospective trial/study, *RS* retrospective series, *NA* not available, *FISI* Fecal Incontinence Severity Index

[a] Cleveland Clinic Fecal Incontinence Score 0–20 unless stated otherwise

[b] Continuation of the same cohort

Table 5 Sacral nerve stimulation

Author	Publication	Year	*n/n* (test/definitive)	Study design	FI severity score[a] (range)		F/U (months)	Functional success rate (%)		Failures (%)	Complications (%)
					Before	After		Complete continence	>50 % improvement		
Ripetti et al. [36]	Tech Coloproctol	2002	16/4	PT	12.2	NA	24	0	100	0	0
Rasmussen et al. [37]	Dis Colon Rectum	2004	45/37	NA	16	6[b]	6	NA	86	8	5
Jarrett et al. [38]	Br J Sur	2004	266/149	SR	15.2	5[b]	1–99	41–75	75–100	NA	12
Conaghan and Farouk [39]	Dis Colon Rectum	2005	5/3	PT	NA	NA	18–24	67	100	0	0
Gourcerol et al. [40]	Dis Colon Rectum	2007	61/33	PT	14.4	NA	12	18	69	31	NA
Melenhorst et al. [41]	Colorectal Dis	2007	134/100	PT	NA	NA	26	NA	79	21	NA
Hetzer et al. [42]	Arch Surg	2007	44/37	PT	14	5[b]	13	NA	77	NA	22
Dudding et al. [43]	Br J Surg	2008	70/51	PT	NA	NA	24	29	85	19	20
Munoz-Duyos et al. [44]	Br J Surg	2008	43/29	PT	NA	NA	35	48	61	7	65[c]
Chan and Tjandra [45]	Dis Colon Rectum	2008	60/53	PRT	16	1.2[b]	12	47.2	71	0	0
Vitton et al. [46]	Dis Colon Rectum	2008	5/5	PT	NA	NA	14	NA	100	0	NA
Roman et al. [47]	Neurogastroenterol Motil	2008	18/18	PT	14.9	4.9[b]	3	NA	78	22	NA
Boyle et al. [48]	Dis Colon Rectum	2009	15/13	PT	12	9[b]	NA	NA	77	13	NA
Altomare et al. [49]	Dis Colon Rectum	2009	94/60	PT	15	5[b]	74	18	75	10	13.3
Vallet et al. [50]	Colorect Dis	2010	45/32	PT	16.1	6.9[b]	44	4	51	21	34
Michelsen et al. [33]	Dis Colon Rectum	2010	167/126	RS	16	10[b]	24	NA	54	12	2.3
Dudding et al. [51]	Int J Colorectal Dis	2010	9/8	RS	NA	NA	46	33	78	22	NA
Boyle et al. [52]	Dis Colon Rectum	2011	50/40	PT	15	8[b]	17	26	54	20	13.6
Lim et al. [53]	Dis Colon Rectum	2011	80/53	RS	11.5	8[b]	51	NA	NA	NA	6.6
Wexner et al. [54]	Ann Surg	2010	133/120	PT[e]	39[f]	30[b]	12	40	87	NA	5
Mellgren et al. [55]	Dis Colon Rectum	2011	133/120	PT	39.9[f]	28[b]	36	40	86	NA	10
Devroede et al. [56]	Female Pelvic Med Reconstr Surg	2012	133/120	PT	39.9[f]	28[b]	40	34	87	NA	NA
George et al. [57]	Dis Colon Rectum	2012	25/23	PT	20[g]	7.5[b]	114	56	100	9[d]	22
Hull et al. [60]	Dis Colon Rectum	2013	76	PT[e]	38[f]	28	≥60	36	89	22/120[e]	35.5 (27/76)

FI fecal incontinence, *F/U* follow-up, *PT* prospective trial/study, *SR* systematic review, *PRT* prospective randomized trial, *RS* retrospective series, *NA* not available

[a] Cleveland Clinic Fecal Incontinence Score 0–20 unless stated otherwise

[b] $p < 0.0001$

[c] Minor complications

[d] Delayed failure

[e] Continuation of patients from original cohort with ≥ 5 years follow-up

[f] Fecal Incontinence Severity Index

[g] St. Mark's score

Table 6 Posterior tibial nerve stimulation

Author	Publication	Year	*n*	Study design	FI severity score[a] (range or SD)		F/U (months)	Functional success rate (%)		Failures (% or *n*/*N*)	Complications (%)
					Before	After		Complete continence	>50 % improvement		
Shafik et al. [67]	Eur Surg Res	2003	32	PT	17.4 ± 2.3	1.7 ± 0.6	16–20	Unclear	53	21.8 %	0
Queralto et al. [68]	Int J Colorect Dis	2006	10	PT	11.4 (1–15)	2.8 (0–10)	4	40	60	20 %	0
Mentes et al. [69]	Tech Coloproctol	2007	2	CR	10–13	7–9	1	0	0	0	0
de la Portilla et al. [70]	Dis Colon Rectum	2009	16	PT	13.2 ± 4.1	8.1 ± 5.7	8	0	60	0 %	0
Vitton et al. [71]	Inflamm Bowel Dis	2009	12 (IBD)	PT	13.25 (7–17)	12.25 (1–17)	3	0	8.3 (1/12)	8/12	0
Eleouet et al. [72]	Int J Colorect Dis	2010	32	PT	14.5 ± 2	11.0 ± 4	6	0	32	37.5 %	0
Vitton et al. [73]	Int J Colorect Dis	2010	24	PT	14 (9–19)	12 (1–19)	3	0	54	0	0
Govaert et al. [74]	Colorectal Dis	2010	22	PT	11.6 (9.5–13.6)	8.2 (6.7–9.7)	12	0	59		13 mild (gastrodynia, temporary leg numbness)
Findlay and Maxwell-Armstrong [75]	Br J Nurs	2010	13	PT	19.75/28 (mean, ICIQ-BS score)	15.33/28 (mean, ICIQ-BS score)	3	0	50	20 %	0
Boyle et al. [76]	Dis Colon Rectum	2010	31	RS	13 (5–20)	7 (0–20)	9	12	67	10 %	
Hotouras et al. [77]	Int J Colorect Dis	2012	88	PT	11.5 ± 4.8	8.4 ± 5.5	6	0	NA	0 %	0
Thomas et al. [126]	Dis Colon Rectum	2013	17	PT	20	19	1.5	12	59	29 %	0

FI fecal incontinence, *F/U* follow-up, *PT* prospective trial/study, *CR* case report, *RS* retrospective series, *IBD* inflammatory bowel disease, *ICIC-B* International Consultation on Incontinence Questionnaire Anal Incontinence Symptoms and Quality of Life, Module B, *NA* not available

[a] Cleveland Clinic Fecal Incontinence Score 0–20 unless stated otherwise

Table 7 Pudendal nerve stimulation

Author	Publication	Year	*n*	Study design	FI severity score	F/U (months)	Success rate (%)		Failure rate (%)	Complications (%)
							Complete continence	>50 % improvement		
Bock et al. [81]	Techn Coloproctol	2010	2	CR	NA	NA	100 %	NA	0	NA
George et al. [79]	Colorectal Dis	2011	20	RS	NA	12	NA	70	NA	<10

FI fecal incontinence, *F/U* follow-up, *CR* case report, *RS* retrospective series, *NA* not available

[a] Cleveland Clinic Fecal Incontinence Score 0–20 unless stated otherwise

Table 8 Pudendal nerve decompression

Author	Publication	Year	n	Study design	FI severity score	F/U (months)	Success rate (%)		Failure rate (%)	Complications (%)
							Complete continence	>50 % improvement		
Beco et al. [82]	Gynecology	2004	5[a]	RS	NA	24	3	2	0	18[b]

FI fecal incontinence, *F/U* follow-up, *RS* retrospective series, *NA* not available

[a] Only 5/32 patients had a decompression alone

[b] Reported from a case series of 32 patients

- Specific: Rectal inflammation in six patients requiring oral antibiotics, abscesses in two patients.

Benefit/risk profile Based on moderate quality evidence, the overall risks of this procedure are low, while the efficacy in improving symptoms of fecal incontinence is low to intermediate (GRADE recommendation: 2B).

Overall cost Material cost (approximately $2,900, added to practice expense).

Physician reimbursement Carrier-priced (see Table 14 in Appendix 2).

Current procedural terminology (CPT) code Unlisted anal procedure (46999), category II code for drug injection (J3490).

Method: Injection of anal canal with traditional injectable bulking agents (carbon/teflon/silicon beads, collagen, fat)

FDA approval Not for fecal incontinence; FDA-approved for urinary incontinence and vesicoureteral reflux.

Goal of procedure Injection of traditional bulking agents into the anal canal in order to expand the tissue and lead to improve the seal of the anal canal and hence prevent passive fecal incontinence.

Description of technique An 18 gauge, 2.5-inch needle with a ratchet gun is inserted through the perianal skin approximately 2 cm from the anal margin; it is targeted at the intersphincteric space around the internal anal sphincter (IAS) from just above the dentate line to the level of the puborectalis sling. Use of endoanal ultrasound guidance was shown to be beneficial in improving the quality of the injection. At the site of an IAS defect, 2.5 ml is injected, and also at the 2, 4, 8, and 10 o'clock positions. The finger should be able to feel the 'bulge' at the site of the injection. Injection into the submucosa of the anal canal should be avoided as it could cause erosion and ulceration.

Setting Office or outpatient facility. Moderate sedation with local anesthesia or general anesthesia. Prophylactic antibiotics are indicated.

Summary of published evidence (Table 3) While there are a number of mostly prospective studies on this topic, most studies are limited by diverse implant materials (teflon, carbon beads, collagen), varying injection sites (intersphincteric space vs. submucosal) as well as small case numbers [9–23]. One significant study was a prospective study with 82 patients (64 females, mean age 66 years) with severe fecal incontinence associated with low anal resting pressure caused by internal anal sphincter dysfunction/defects [11]. The patients were randomized into two groups—one having the beads implanted with ultrasound guidance, and the other one not. Both groups were similar in age, gender, past anorectal surgery, and duration of follow-up (median of 6 months; range 1–12 months). Baseline continence scores were identical at 14.5 (range 10–20). There was a significant improvement in fecal continence in both groups at all timepoints, but by 12 months the ultrasound-guided implants were associated with a significantly better improvement of incontinence scores of more than 50 %. The authors recommended intersphincteric injection rather than submucosal injection to minimize the possibility of erosion and ulceration, but that question has not been

Table 9 Artificial bowel sphincter

Author	Publication	Year	n	Study design	FI severity score[a] (range or SD)		F/U (months)	Functional success rate (%)		Failures (n/N)	Complications (n/N)
					Before	After		Complete continence	>50 % improvement		
Wong et al. [85]	Dis Colon Rectum	1996	12	RS	NA	NA	58	57 (4/7)	100 (9/9)	5/12	4/12
Vaizey et al. [86]	Lancet	1998	6	RS	19 (18–20)	3 (0–6)	10	60 (3/5)	100 (5/5)	1/6	3/6
Lehur et al. [87]	Int J Colorect Dis	1998	13	RS	(14–20)	(0–10)	30	55 (6/11)	91 (10/11)	4/13	9/13
Christiansen et al. [88]	Ann Surg	1999	17	RS	5/5 (no range, Williams scale)	2.5/5 (1–4, Williams scale)	84	50 (4/8)	100 (8/8)	7/15	6/15
O'Brien and Skinner [89]	Dis Colon Rectum	2000	13	RS	18.7 ± 1.6	2.1 ± 2.6	NA	90 (9/10)	100 (10/10)	3/13	8/13
Dodi et al. [90]	Colorectal Dis	2000	8	RS	96.2 (70–108, AMS score)	19.4 (0–61, AMS score)	11	68 (4/6)	100 (6/6)	2/8	4/8
Lehur et al. [91]	Dis Colon Rectum	2000	24	RS	106/120 (± 13, AMS score)	25/120 (± 32, AMS score)	20	83 (15/18)	100 (18/18)	8/24	14/24
Altomare et al. [92]	Br J Surg	2001	28	RS	14.9 (11–20)	2.6 (0–6)	19	NA	100 (21/21)	7/28	7/28
Ortiz et al. [93]	Br J Surg	2002	22	RS	18 (14–20)	4 (0–14)	28	60 (9/15)	93 (14/15)	9/22	17/22
Wong et al. [94]	Dis Colon Rectum	2002	112	PT	106/120 (71–120, AMS score)	51/120 (0–108, AMS score)	12	NA	74 (51/69)	41/115	99/115
Lehur et al. [95]	Dis Colon Rectum	2002	16	RS	105/120 (± 14, AMS score)	23/120 (± 22, AMS score)	25	NA	100 (11/11)	5/16	7/16
Devesa et al. [96]	Dis Colon Rectum	2002	53	RS	17 (10–20)	4 (0–14)	26	NA	31 (13/42)	10/52	23/52
Romano et al. [105]	Dis Colon Rectum	2003	8	RS	NA	4.3	17	0 (0/8)	63 (5/8)	0/8	5/8
Parker et al. [106]	Dis Colon Rectum	2003	47 (−2)	RS	103/120 (74–120, AMS score)	59/120 (0–108, AMS score)	65	NA	NA	22/47	47/47
Michot et al. [107]	Ann Surg	2003	(12 +) 25	RS	NA	NA	34	79 (15/19)	63 (12/19)	5/25	10/25
Ortiz et al. [108]	Int J Colorect Dis	2003	8	PT	16	8	44	NA	40 (2/5)	3/8	10/8
O'Brien et al. [109]	Dis Colon Rectum	2004	7	PRT	19.0 ± 1.2	4.8 ± 4.0	6	NA	100 (6/6)	1/7	5/7
Casal et al. [110]	Colorectal Dis	2004	10	PT	99.9/120 (83–120, AMS score)	28.4 (0–58)	29	NA	86 (6/7)	3/10	7/10
Altomare et al. [97]	Br J Surg	2004	28	RS	14.9 (11–20, from 2001 ref)	NA	50	NA	18 (3/17)	11/28	7/28

Table 9 continued

Author	Publication	Year	n	Study design	FI severity score[a] (range or SD)		F/U (months)	Functional success rate (%)		Failures (n/N)	Complications (n/N)
					Before	After		Complete continence	>50 % improvement		
DaSilva et al. [98]	Dis Colon Rectum	2004	11	RS	18	7.5	20	NA	73 (8/11)	0/11	5/11
Mundy et al. [99]	Br J Surg	2004	350 from 14 studies	SR	15–19 CCFIS 95–106 AMS	2–4.5 CCFIS 5.5–48 AMS	Variable		238/350	109/350	
Melenhorst et al. [100]	Int J Colorect Dis	2008	33 (34)	RS	4.8/5 (3–5, Williams score)	2.1/5	17	69 (18/26)	81 (21/26)	8/33	9/34
Ruiz Carmona et al. [101]	Colorectal Dis	2009	17	RS	17.5	9	68	44 (4/9)	100 (9/9)	8/17	17/17
Wexner et al. [102]	Dis Colon Rectum	2009	51 (47 pts)	RS	18 ± 1.4 (0–20)	NA	39	NA	NA	13/51	25/51
Michot et al. [103]	Dis Colon Rectum	2010	32	RS	18.4	6.8 (0–14)	41	48 (11/23)	>83 (19–23/23)	9/32	8/32
Wong et al. [104]	Ann Surg	2011	52	RS	16.7 (12–20)	5.6 (0–17)	64	NA	67 (35/52)	14/52	26/52

FI fecal incontinence, *F/U* follow-up, *RS* retrospective series, *PT* prospective trial/study, *PRT* prospective randomized trial, *SR* systematic review, *NA* not available, *CCFIS* Cleveland Clinic Fetal Incontinence Score

[a] CCFIS 0–20 unless stated otherwise

Table 10 Magnetic ring

Author	Publication	Year	*n*	Study design	FI severity score[a] (range or SD)		F/U (months)	Functional success rate (%)		Failures (*n*/*N*)	Complications (*n*/*N*)
					Before	After		Complete continence	>50 % improvement		
Lehur et al. [111]	D is Colon Rectum	2010	14	Prospective, observational feasibility study	17 (12–19)		6 (median)	NA	Mean weekly FI episodes 7.2 to 0.7 7/10 with Wexner score below 10	3 explants	7/14 4/7 minor 3/7 major
Wong et al. [112]	Dis Colon Rectum	2011	10	Case-matched comparing magnetic sphincter with artificial bowel sphincter	17 (13–19)	6	8 (median)	NA	NA	1 extruded Otherwise not stated	1 device extrusion1 constipation2 mild rectal bleeding
Wong et al. [113]	Colorectal Dis	2012	12	Non-randomized comparativeConsecutive patients failing SNS were implanted with the magnetic device and then compared with the SNS group	16.5 (11–19)	to 6 (3–15)	18 (8–30)	NA	NA	Only reported as one explant extrusion	2 mild anal bleeding1 fecal impaction1 device extrusion2 implanted needed daily diarrhea medications

FI fecal incontinence, *F/U* follow-up, *SNS* sacral nerve stimulation, *NA* not available

[a] Cleveland Clinic Fecal Incontinence Score 0–20 unless stated otherwise

systematically studied. Other studies targeted the submucosal layer of the anal canal. The literature remains weak but the technique may have some merit in patients with isolated IAS defect or anal canal asymmetry.

Indications for this procedure

- Mild to moderate fecal incontinence (CCFIS 1–14) caused by IAS dysfunction or defect
- Anal canal asymmetry (e.g. keyhole deformity)
- Failed conservative treatment (dietary, fiber supplements, loperamide, and sphincter exercises)
- Failed sphincteroplasty

Contraindications for procedure

- Pregnancy
- Active perianal sepsis or fistula
- Unresected anorectal cancer
- Immunocompromised patients
- Inflammatory bowel disease
- Chronic idiopathic diarrhea

Complications

- General: Pain, bleeding, infection.
- Specific: Chronic anal pain, bead migration, erosion of implants, fistula formation.

Benefit/risk profile Based on moderate quality evidence, the overall risks of the procedure are low, while the efficacy in improving symptoms of fecal incontinence is low (GRADE recommendation: 2C).

Overall cost Facility-based.

Physician reimbursement Carrier-priced.

CPT code Unlisted anal procedure (46999).

Induction of scarring and remodeling

Method: Radiofrequency energy delivery

FDA approval 2002.

Goal of the procedure The radiofrequency energy procedure involves a thermo-controlled delivery of radiofrequency energy to the anal canal in order to create thermal lesions in the muscle while preserving the mucosal integrity. The exact mechanisms of action to increase the outlet resistance and possibly improve sensation remain unknown, but a combination of scarring and sphincter remodeling (collagen, fibroblasts/myoblasts) has been postulated.

Description of the technique The device is inserted into the anal canal whereby the transparent material allows direct visualization and alignment at the dentate line. A set of four needle electrodes are deployed into the tissue to deliver energy for 60 s. The thermal injury is intended to occur at the needle tip while the mucosa is cooled by

Table 11 Perineal sling

Author	Publication	Year	n	Study design	FI severity score[a]		F/U (months)	Functional success rate (%)		Failures (n/N)	Complications (n/N)
					Before	After		Complete continence	>50 % improvement		
Greene [116]	Arch Surg	1985	8	RS	Severe	Mild	>6	7/8	8/8	0/8	0/8
O'Rourke and Egerton [117]	Aust N Z J Surg	1985	18 (24)	RS	NA	NA	36	NA	60 (11/18)	7/18	9/18
Yamana et al. [118]	Dis Colon Rectum	2004	8	RS	13 (CCFIS) 27 (FISI)	5 (CCFIS) 9 (FISI)	6	NA	NA (6/7)	1/8	2/8
Shobeiri et al. [119]	Obstet Gynecol	2009	1	CR	NA	NA	12	100 (1/1)	100 (1/1)	0	0

FI fecal incontinence, *F/U* follow-up, *RS* retrospective series, *CR* case report, *NA* not available, *CCFIS* Cleveland Clinic Fecal Incontinence Score, *FISI* Fecal Incontinence Severity Index

[a] CCFIS 0–20 unless stated otherwise

chilled water at the base of each needle. The temperature is monitored in real-time and power automatically stopped if it exceeds 85 °C. Typically, all four quadrants are sequentially treated at four different levels within the anal canal.

Setting Outpatient in endoscopy suite or ambulatory surgery center. Conscious sedation or anesthesia.

Summary of published evidence (Table 4) The application of the radiofrequency energy to a sphincter structure was first introduced to and tested in patients with gastroesophageal reflux disease (GERD) before it was adapted to patients with fecal incontinence. For GERD, the technique appears to have a positive short- and long-term impact on the patients' subjective symptoms and on the objective degree of esophagitis.

The evidence reported in the literature for the treatment of fecal incontinence is relatively sparse and has relevant limitations. Six prospective patient series were published in eight prospective reports [24–31] and one retrospective series [32]. In general, the studies had rather small case numbers and overall short follow-up of 6–12 months. Only one series that was reported at three different timepoints [24–26] had more than 12 months' follow-up. The largest cohort was a prospective, multicenter trial in the US that enrolled 50 patients [27]. While some of the studies reported a statistically significant improvement of the incontinence, the clinical relevance of the marginal degree of benefit remains debatable at best. Complications included pain, ulcerations, and bleeding.

Indications for this procedure

- Mild to moderate treatment-refractory incontinence (CCFIS 1–14) with or without IAS defect.

Contraindications (relative/absolute) for this procedure

- Absolute contraindications: Active fissure, fistula, tumor, history of injection/implantation of foreign material (including beads or dextranomer).
- Relative contraindications: Severe stricture of anorectal canal. History of rectovaginal fistula. History of inflammatory bowel disease.
- Caution: History of radiation treatment.

Complications

- General: Pain, bleeding, infection.
- Specific: Mucosal ulcerations, formation of rectovaginal fistula, local hematoma, worsening fecal incontinence (particularly in the first 6 weeks).

Benefit/risk profile Based on moderate-quality evidence, the overall risks of the procedure are low, while the efficacy in improving symptoms of fecal incontinence is low to intermediate (GRADE recommendation: 2B).

Overall cost Facility based.

Table 12 Cecal/sigmoid trapdoor button

Author	Publication	Year	*n*	Study design	FI severity score[a] (SD)		F/U (months)	Functional success rate (% or n/N)		Failures (*n*/*N*)	Complications (%)
					Before	After		Complete continence	>50 % improvement		
Becmeur et al. [120]	J Pediatr Surg	2008	29	RS	NA	NA	NA	NA	17/20	NA	NA
Holbrook and Tsang [121]	Surg Laparosc Endosc Percutan Tech	2012	5[b]	CR	NA	NA	NA	NA	NA	NA	NA
Yamout et al. [122]	Pediatr Surg Int	2009	17	RS	NA	NA	46 ± 21	NA	NA	NA	Multiple
Chereau et al. [123]	Colorectal Dis	2011	75[c]	RS	NA	3.4 ± 2.4	48	NA	NA	NA	16
Siddiqui et al. [124]	J Pediatr Gastroenterol Nutr	2011	105[c]	RS	NA	NA	6	NA	69 %	NA	63

FI fecal incontinence, *F/U* follow-up, *RS* retrospective series, *CR* case report, *NA* not available

[a] Cleveland Clinic Fecal Incontinence Score 0–20 unless stated otherwise

[b] Done for constipation

[c] Appendicostomy used, not trapdoor button

Physician reimbursement Carrier-priced.

CPT code Category III, 0288T (Anoscopy w/rf delivery).

Category II: Stimulation/improvement of neuromuscular function

Method: Sacral nerve stimulation (SNS)

FDA approval 2011.

Goal of the procedure Reduction in frequency of episodes or days of fecal incontinence, by at least 50 % based on a 2-week diary. The exact mechanism of action is unclear. However, it is felt that SNS may modulate rectal sensation activating or deactivating chemical mediating receptors [33]. SNS is also thought to stimulate the afferent pathway and change brain activity relevant to the continence mechanism [34].

Description of the technique SNS is performed in two stages (stage 1, trial phase; stage 2, definitive implant). Stage 1 is diagnostic and involves placement of leads into the S3 foramen that are connected to an external stimulator. If stage 1 leads to at least a 50 % improvement of fecal incontinence symptoms (as recorded on a diary or by means of an incontinence score), stage 2 with implantation of a definitive stimulator is carried out 2 weeks later.

Setting Both stages are performed in an outpatient setting. Stage 1 involves a combination of light sedation and a local field block. The patient is awake at the time of the lead placement. Stage 2 is performed with the patient in deep sedation and local field block.

Summary of published evidence (Table 5) Even though SNS only recently obtained FDA approval for use in fecal incontinence, it had been widely used for urinary incontinence previously and gained worldwide traction for fecal incontinence since the first trial in Europe was reported in Lancet in 1995 [35]. Overall, 50–100 % of patients undergoing a definitive SNS implant experienced a statistically significant greater than 50 % improvement of continence after a mean follow-up of 3–99 months [33, 36–57].

While at the same time numerous studies on overlapping sphincteroplasty demonstrated a disappointing decline in long-term efficacy for fecal incontinence secondary to sphincter injury, there has been a growing interest in using SNS rather than sphincteroplasty even in patients with traumatic fecal incontinence. Recent studies showed that SNS was effective even in patients with fecal incontinence secondary to sphincter injury. The results of one study, with 77 % of patients having more than 50 % improvement in symptoms, have been reproduced by others [39, 45, 48, 58, 59]. In a systemic review of ten studies ($n = 119$), the average CCFIS dropped from 16.5

to 3.8 [58]. A prospective, randomized trial comparing SNS with a medically managed control group showed 100 % continence in 41.5 and 75–99 % improvement based on the CCFIS in 24.4 % of SNS patients. These favorable results were achieved despite a significant number of patients having sphincter defects of up to 120° [45]. Unlike the less favorable outcome of overlapping sphincteroplasty in patients with pudendal neuropathy, patients with unilateral or bilateral pudendal neuropathy undergoing SNS were shown to experience an improvement in CCFIS from 15 to 5 [59]. In the US, FDA approval in 2011 for SNS for fecal incontinence followed a thoroughly scrutinized large, prospective, non-randomized, multicenter study conducted in 14 centers across the US, one center in Canada, and one center in Australia. The results, presented in three studies, showed that 87 % of patients had a greater than 50 % improvement and 34 % of even complete continence at 40 months; there was no deterioration of fecal incontinence over time [54–56, 60].

Although the results of SNS in fecal incontinence overall are clearly very encouraging, it should be noted that data on its use in patients with fecal incontinence following low anterior resection (LAR) for rectal cancer, ileal pouch-anal anastomosis (IPAA) and rectal prolapse are sparse at best. Few studies showed a favorable response in patients after LAR for rectal cancer [61, 62]. Its positive effect in IPAA is restricted to one case report [63]. A retrospective review and a multicenter trial noted a significant improvement in CCFISs from 15 to 5 in patients who had undergone abdominal and perineal repair of rectal prolapse [64, 65]. Interestingly, there is one small study evaluating SNS in patients with fecal incontinence secondary to severe perianal Crohn's disease [46]. These subgroups of patients have a very complex disease process that not uncommonly requires a permanent diversion. The small case series ($n = 5$) showed 50 % improvement in CCFIS with SNS; however, large prospective studies will be necessary to validate these results for fecal incontinence in patients with surgically altered pelvic and rectal anatomy.

SNS is relatively safe, with reported complications in the range of 0–34 %. However, one European study reported 64 % adverse events, but these were fairly minor events without impact on the overall outcome. The large, prospective, non-randomized trial showed a good safety profile; the post-implant infection rate was at 11 % without permanent morbidity, but surgical intervention was required in six patients [55].

In conclusion, SNS proved to a very effective treatment in patients not responding to non-operative management of fecal incontinence. It could be used as the first-line of surgical management of fecal incontinence due to idiopathic causes, moderate sphincter defect and pudendal nerve neuropathy. However, its role after surgery for rectal cancer (LAR), prolapse, and IPAA will have to await larger studies for definitive validation.

Indications for this procedure

- Moderate to severe incontinence (CCFIS 7–20)
- Failure to respond to conservative management
- Absent or only moderate sphincter defects (internal or external)
- Pudendal neuropathy
- Limited data available: failed sphincteroplasty, incontinence after proctectomy with coloanal anastomosis

Contraindications (relative/absolute) for this procedure

- Absolute contraindications: Mechanical obstruction (urinary or bowel), congenital anorectal malformations (Hirschsprung's disease, imperforate anus), untreated rectal prolapse, deformity of sacral spine, skin disease (e.g. pyoderma, pilonidal disease).
- Relative contraindications: Bleeding disorders (uncorrected).
- Caution: safety has not been established in pregnancy, pediatric age group, or in patients with progressive neurologic disease. Magnetic resonance imaging (MRI): while newer SNS models may be compatible with MRI of the head only, it is recommended to check with the device company.

Complications

- General: Pain at the site of implant (28 %), bleeding, infection (11 %).
- Specific: Lead displacement/fracture, paresthesia (15 %), change in the sensation of stimulation (12 %), urinary incontinence (6 %), diarrhea (6 %), extremity pain (6 %).

Benefit/risk profile Based on a good body of moderate quality evidence, the overall risks of the procedure are low to moderate, while the efficacy in improving symptoms of fecal incontinence is moderate to high intermediate (GRADE recommendation: 1B).

Physician reimbursement: Based on established CPT codes

- 64561 Percutaneous transforaminal lead placement
- 64581 Incision for implanting of neurostimulator
- 64585 Lead revision or removal
- 64595 Generator revision or removal
- 95972 Analysis and reprogramming codes
- 76000 Fluoroscopy (separate procedure), up to 1 h of physician time

Method: Posterior tibial nerve stimulation (PTNS/TENS)

FDA approval No.

Goal of the procedure The percutaneous tibial nerve stimulation (PTNS), aka transcutaneous electrical nerve stimulation (TENS), is a procedure expected to reduce episodes of incontinence to solid and liquid stool. The mechanism of action is unknown but it has been hypothesized that posterior tibial nerve stimulation results in favorable central nervous effects within the cortex [66]. Suprasacral neural centers involving associative cortical areas mediate the efficacy by elaboration of the stimulus.

Description of the technique The procedure is performed with the patient seated or reclining. A needle electrode is inserted percutaneously just above and medial to the ankle; a surface electrode is placed in the arch of the same foot. The needle electrode is connected to a low-voltage stimulator. Current is adjusted based on the response of plantar flexion or toe fanning. Stimulation is carried out for 20–30 min.

Setting Office, outpatient. No sedation needed.

Summary of published evidence (Table 6) There are a number of relatively small prospective and retrospective case series [67–77] but no randomized controlled trials to evaluate this therapy for fecal incontinence. Incontinence scores improved after stimulation, with an average of 52 % of patients reporting 50 % or more improvement; however, achievement of complete control was the exception. On the other hand, posterior tibial stimulation as a minimally invasive outpatient procedure was safe, with only two adverse events reported in 194 patients.

Indications for this procedure

- Mild to moderate fecal incontinence to liquid and solid stool (currently only in the presence of associated urinary incontinence).
- Fecal incontinence associated with or without an external anal sphincter defect [77].
- Fecal incontinence associated with inflammatory bowel disease.

Contraindications (relative/absolute) for this procedure

- Absolute contraindications: Leg sepsis.
- Relative contraindications: Leg edema, bleeding disorders (uncorrected).

Complications

- General: Pain, bleeding, infection.
- Specific: Mild adverse effects reported in three patients: gastrodynia in two patients and temporary leg numbness in one patient.

Benefit/risk profile The risks of the procedure are low. Based on very limited evidence of limited quality, the efficacy in improving symptoms of fecal incontinence is low in patients with moderate to severe symptoms, but potentially higher in patients with only mild symptoms (GRADE recommendation: 2C). In the absence of FDA approval, only patients who have both urinary and mild to moderate fecal incontinence can currently be offered this treatment under supervision of the urologists.

Physician reimbursement Very difficult to obtain carrier pricing not FDA approved for fecal incontinence.

CPT code No code available for fecal incontinence at this time (64566 for urinary incontinence).

Method: Pudendal nerve stimulation (PNS)

FDA approval No (even though the same device is FDA-approved for SNS).

Goal of the procedure The pudendal nerve which receives its contributions from nerve roots S2–S4 is the primary motorneuron of the sphincter complex. It is speculated that direct stimulation of this combination of roots should allow for more efficient stimulation than stimulation of S3 only by means of SNS [78].

Description of the technique The technique involves the introduction of a lead introducer at the ischial spine, whereby a gloved finger within the rectum guides the introducer towards the pudendal nerve within Alcock's canal. Proper positioning is confirmed by contraction of the anal sphincters, when the stimulation wire connected to the external neurostimulator is activated. Once satisfactory results are achieved, a pulse generator similar to the sacral nerve stimulator is implanted 2 weeks later [79].

Setting Outpatient procedure, general anesthesia, prone position.

Summary of published evidence (Table 7) Prior studies in the urology literature have shown that pudendal nerve stimulation (PNS) may be better than SNS in neurogenic bladder disorders [80]. However, for fecal incontinence, PNS is a relatively new concept, with published data limited to 22 patients [79, 81]. Prospective and preferably randomized trials should be considered to compare results and outcomes of PNS with SNS.

Indications for this procedure

- Patients who are not candidates for SNS secondary to anatomical abnormality of the spine.
- Moderate to severe incontinence (CCFIS 7–20).
- Failure to respond to conservative management.

Contraindications (relative/absolute) for this procedure

- Absolute contraindications: Mechanical obstruction (urinary or bowel).
- Relative contraindications: Bleeding disorders (uncorrected).
- Caution: safety has not been established in pregnancy, pediatric age group, or patients with progressive neurologic disease. MRI: while newer SNS/PNS models may be compatible with MRI of the head only, it is recommended to check with the device company.

Complications

- General: Pain at the site of implant, bleeding, infection.
- Specific: Lead displacement/migration, injury to neurovascular bundle.

Benefit/risk profile Based on anecdotal evidence of limited quality, there are insufficient data to conclude on the safety and efficacy in improving symptoms of fecal incontinence (GRADE recommendation: 2C).

Physician reimbursement Carrier priced.

CPT code 46999, unlisted procedure code.

Method: Pudendal nerve decompression

FDA approval Not applicable.

Goal of the procedure This procedure is expected to restore continence associated with chronic anal pain due to pudendal nerve compression (nerve entrapment).

Description of the technique Under anesthesia, the pudendal nerves are bilaterally exposed and released through a transgluteal approach by cutting either the sacrospinal or sacrotuberous ligament.

Setting Inpatient. General anesthesia.

Summary of published evidence (Table 8) Pudendal nerve decompression for anal incontinence has only been reported as a single case series that was part of a retrospective study on pudendal neuralgia [82]. No studies have been reported for fecal incontinence as a primary complaint with or without pain.

Indications for this procedure Unknown, possibly pudendal neuralgia (with/without fecal incontinence)

Contraindications for this procedure Unknown

Complications

- General: Pain, bleeding (pudendal artery), infection, delayed wound healing.
- Specific: Clitoral pain (transient), nerve injury.

Benefit/risk profile The procedure is not recommended for treatment of fecal incontinence but for intractable pudendal neuralgia. The overall risks of the procedure are moderate; however, based on the lack of true evidence, the efficacy in improving symptoms of fecal incontinence alone has not been documented. The procedure is not recommended for fecal incontinence as the primary symptom and/or the absence of pudendal neuralgia (GRADE recommendation: 2C).

Physician reimbursement Carrier priced.

CPT code 46999, unlisted procedure code.

Method: Femoral nerve transfer

FDA approval Not available.

Goal of the procedure This procedure is expected to restore control to denervated muscles supplied by the pudendal nerve.

Description of the technique The procedure has only been described in cadavers and dogs [83, 84]. A perineal approach is used to identify the pudendal nerve in Alcock's canal and the femoral nerve in the anterior thigh. The femoral nerve branch to the vastus lateralis muscle is transferred to the pudendal nerve in Alcock's canal whereby nerve stretching should be avoided [83].

Setting No human studies conducted.

Summary of published evidence There has been no published evidence in humans. Femoral nerve transfer is an experimental procedure that has only been performed in animals and cadaveric studies [83, 84]. Currently, there is no indication for this application in humans.

Indications for this procedure Unknown, possibly fecal incontinence due to peripheral neuropathy.

Benefit/risk profile This procedure is currently not recommended. The efficacy in improving symptoms of fecal incontinence is not documented in human studies; the risks of such an intervention are therefore not justifiable. The procedure is not recommended for fecal incontinence as a primary symptom.

Physician reimbursement Unknown.

CPT code None.

Category III: Replacement of sphincter function

Method: Implantation of an artificial bowel sphincter (ABS)

FDA approval 2001, 2012.

Goal of the procedure An artificial bowel sphincter (ABS) device is completely implanted in order to achieve two goals: (1) to establish a sufficient closure of the anal canal by means of extrinsic hydraulic compression to resist the accidental loss of stool; and (2) to allow a dynamic

opening of the anal canal for planned passage and controlled evacuation of stool.

Description of the technique The neosphincter consists of three fluid-filled components that are linked together by kink-resistant tubing. During surgery, the inflatable cuff (actual sphincter) is inserted through small perianal incisions and locked around the anus. From there, the tubing is passed to a second, suprapubic incision which is used for the other two components. Using Hegar dilators, one pocket is created under the skin for the control pump—in females in the labia, in males in the scrotum (typically opposite to the patient's dominant hand). A second pocket is created in the extraperitoneal space behind the rectus muscle (prevesical/retropubic Retzius space or extraperitoneal iliac fossa) for a pressure-regulating balloon reservoir. Once the connections are made, the default position is that the pressurized cuff closes off the anus; squeezing the bulb on the control pump opens the anus by transferring fluid from the perianal cuff to the balloon. Pressure from the balloon slowly forces the fluid passively back into the cuff, which closes the anus after several minutes. The process can be repeated if evacuation of stool is incomplete.

Setting Inpatient. General anesthesia.

Summary of published evidence (Table 9) After the first case report on its efficacy in 1987, the ABS was officially introduced in 1996. Prior to that, extensive experience has accumulated with a similar FDA-approved device for patients with urinary incontinence. Subsequently, a number of publications became available, including a prospective, multicenter cohort study in the US which eventually reflected the basis for FDA approval in 2001 [85–107]. The majority of reported series were retrospective analyses, and only a limited number of prospective data were published [94, 108–110]. With very few exceptions, the studies documented the high degree of improvement in fecal incontinence if the device could be implanted and retained without complications. However, all studies showed a high rate of complications, which included infections (acute and chronic), device erosions, anorectal ulcerations, device malfunction secondary to leaking the fluid, device migration, pain, and constipation. Complications typically occur early in the postoperative period (acute infections, technical problems), or in the later course (erosion, late infections, functional problems such as outlet obstruction). In comparison with other methods, the ABS has a similar rate of complications but is easier and more functional than the dynamic graciloplasty [108]. Compared with SNS, the risks are substantially higher, but the functionality in patients without complications appears to be superior.

Apart from meticulous surgical technique, patient selection for the ABS is crucial for successful outcomes. The ideal patient suffers from moderate to severe incontinence due to a lack of sphincter contractility, and has healthy and elastic tissues with sufficient circumferential space to place the device. In addition, there are less common situations, e.g. the device may be the only option to create a functional condition in patients who anatomically do not have any sphincter, such as patients with a history of imperforate anus or after total anorectal reconstruction after pervious abdominoperineal resection. In the latter situations, restriction and a high degree of caution should be applied before moving forward with such a project. As the blood flow to the very distal segment of a coloanal or ileo-anal anastomosis comes only from proximal, the closing pressure from the ABS may interrupt that flow and trigger an erosion once activated.

Indications for this procedure

- Moderate to severe incontinence (CCFIS 7–20) with sufficient tissue quality and perianal space to take and embed the device.
- Incontinence after failure of sphincteroplasty and SNS.
- Loss of native sphincter function.
- Neurogenic fecal incontinence.
- Incontinence after surgical repair of rectal prolapse with persistent widely patulous anal canal.
- Less common indications: history of imperforate anus, complete abdominoperineal reconstruction after previous abdominoperineal resection.

Contraindications (relative/absolute) for this procedure

- Absolute contraindications: Active infection or open wound, severe tissue induration/rigidity (e.g. post-surgical, post-radiation), lack of sufficient tissue around the anus or the rectovaginal septum, presence of cancer, anoreceptive intercourse.
- Relative contraindications: Incontinence to gas only, functional incontinence with normal anatomy and manometric values at rest and during squeezing, incontinence related to inflammatory bowel disease, non-emptying rectum
- Caution: History of radiation treatment, history of previous device infection/removal.

Complications

1. Acute: Pain, bleeding, infection/sepsis, formation of rectovaginal fistula, primary device failure
2. Chronic: Device failure (fluid loss), erosion, infection

In case of a device infection or erosion, it typically has to be explanted to allow the area to heal. If the device

becomes non-functional due to the loss of fluid, it is often recommended to replace all three device components even if the most likely site is at the cuff.

Benefit/risk profile Based on a body of evidence of moderate quality, the efficacy in improving symptoms of fecal incontinence is high, if there are no complications; however, the overall risks of the procedure are moderate to high as well (GRADE recommendation: 1B).

Overall cost Physician payment, device cost, facility cost. Not included are typically additional cost arising from complications on one hand, and reduced cost from improvement of functionality and control.

Physician reimbursement Carrier priced.

CPT code 46762 sphincteroplasty, anal, for incontinence, adult; implantation artificial sphincter. 53446 removal of device.

Method: Implantation of magnetic ring

FDA approval No. A similar device was FDA-approved in 2012 for esophageal reflux.

Goal of the procedure This is an anal occlusion device consisting of a string of titanium beads with a magnetic core that are implanted to encircle the anus. The act of expelling stool generates sufficient force to break the magnetic attraction, allowing the beads to separate and the anal canal to open (to allow stool passage).

Description of the technique Using an anterior or two anterolateral perianal incisions, a circumferential tunnel is developed toward the coccyx on each side of the anus. A sizer is used to determine the number of beads needed for optimal occlusion and fluoroscopy aids in proper sizer determination. The device (which is essentially a string of these approximated beads threaded on a wire such that they can expand) is placed in the tunnel around the anus and the ends tied. The skin is closed.

Setting General anesthesia. Inpatient, possibly outpatient.

Summary of published evidence (Table 10) For this new device, there have so far only been three published pilot and feasibility studies in France and the US [111–113]. The 'failure' rates, i.e. the number of patients who did NOT improve were not directly stated in any of these three studies. Also, patients were shared in these three studies, and hence the number of patients worldwide and their overall outcome remains unclear. Preliminary impressions suggest that as long as there is enough tissue around the anus to allow for a safe implantation, this device will be feasible. Whether it will be safe and satisfactory for patients born with an imperforate anus, after an LAR or pelvic pouch, is unclear and potentially dependent on the degree of rectal dysfunction. At the present time, more studies would be needed to determine the value of this new device.

The same device received FDA approval in 2012 for use in chronic GERD. A multicenter study with laparoscopically implanted magnetic rings at the gastroesophageal junction was recently published and showed improvement of quality of life in 100 % of patients, and cessation of proton pump inhibitors in 80 % of patients, with no reported long-term device complications [114].

Indications for this procedure

- Severe or mild fecal incontinence.

Contraindications (relative/absolute) for this procedure

- Absolute contraindications: Active infection or open wound, severe tissue induration/rigidity (e.g. post-surgical, post-radiation), lack of sufficient tissue around the anus or the rectovaginal septum, presence of cancer, anoreceptive intercourse, inflammatory bowel disease, immunocompromised patient.
- Relative contraindications: Need for future MRI, incontinence to gas only, functional incontinence with normal anatomy and manometric values at rest and during squeezing, incontinence related to non-emptying rectum.
- Caution: History of radiation treatment, history of previous device infection/removal.

Complications

- General: Pain, bleeding, infection, delayed wound healing.
- Specific: Device infection/sepsis, device extrusion, erosion, fecal impaction/constipation

Benefit/risk profile The overall risks of the procedure are moderate, but there are insufficient data on the efficacy in improving symptoms of fecal incontinence (GRADE recommendation: 1C).

Overall cost Unknown.

Physician reimbursement Carrier priced, but unlikely to receive reimbursement if not FDA-approved.

CPT code Not available.

Method: Perineal puborectalis sling

FDA approval 2007.

Goal of the procedure The goal of this treatment is to treat fecal incontinence by increasing the pelvic floor support and decreasing the anorectal angle. This technique is supposed to work similar to a Parks' post-anal repair.

Description of the technique With the patient in the lithotomy position and after a bowel preparation, a 2 cm incision is made in the suprapubic position. A 3–4 cm curvilinear incision is made posterior to the anus and the intrasphincteric space is opened on either side. A trochar is passed on either side of the rectum from the perineum to the suprapubic incision. A polyester mesh string is passed through each incision and tied anteriorly.

Setting Inpatient, general anesthesia.

Summary of published evidence (Table 11) The technique of a puborectalis sling is not new. Parks emphasized the importance of the anorectal angle and attempted to reconstruct it with the post-anal repair [115]. His results could not be reproduced by others. In the 1980s, an artificial sling was proposed as a tool to control rectal prolapse and fecal incontinence, but the results were mixed and often not satisfying [116, 117]. More recently, the concept has regained traction from similar operations for urogynecological indications (pelvic organ prolapse). For fecal incontinence, there has been one non-randomized case series [118] and anecdotal report [119], such that no conclusions can be drawn. However, currently a trial with a minimally-invasively delivered self-fixating mesh is ongoing for the treatment of pelvic floor weakness in women with symptoms of moderate fecal incontinence (clinicaltrials.gov NCT00565136).

Indications for this procedure Mild to moderate fecal incontinence (CCFIS 4–12) related to pelvic organ descent.

Contraindications (relative/absolute) for this procedure

Absolute contraindications: Active infection or open wound, severe tissue induration/rigidity (e.g. post-surgical, post-radiation), lack of sufficient tissue around the anus, presence of cancer.
Relative contraindication: Incontinence to gas only, functional incontinence with normal anatomy and manometric values at rest and during squeezing, incontinence related to inflammatory bowel disease.
Caution: History of radiation treatment, history of previous device infection/removal.

Complications

General: Pain, bleeding, infection.
Specific: Erosion, fistula formation.

Benefit/risk profile There are insufficient data to assess the overall risks or the efficacy of the procedure in improving symptoms of fecal incontinence (GRADE recommendation: 2C).

Overall cost Not available.

Physician reimbursement Carrier priced.

CPT code None.

Category IV: Reduction of stool load

Method: Percutaneous trapdoor button for Malone antegrade colonic enema (MACE) [cecostomy, sigmoidostomy]

FDA approval 1999.

Goal of the procedure The goal of a Malone antegrade colonic enema (MACE) through the cecum is to irrigate the colon during a defined period of time, under controlled circumstances, to improve the quality of life for patients with incontinence or severe constipation. Historically the appendix, matured to the skin or umbilicus, has been used as a conduit for irrigation. For patients without an appendix, a conventional gastrostomy button has been used 'off label' (until a percutaneous cecostomy catheter was FDA-approved) to create a port for the administration of enema solutions, to facilitate antegrade colonic cleansing for patients with fecal incontinence without interfering with the absorptive capacity of the small bowel.

Description of the technique Placement of the percutaneous cecostomy catheter is done under fluoroscopic or ultrasound guidance using local anesthesia. Placement of the catheter within the cecum is confirmed with contrast. It is a two-stage procedure: the first catheter is temporary and is left in place for approximately 6 weeks while the tract matures. This is then replaced with the permanent device.

The catheter can also be placed laparoscopically, in which case the cecum is usually plicated in addition. Cecal plication is reported to decrease fecal seepage at the insertion site.

Setting The percutaneous procedure can theoretically be carried out in an outpatient setting under sedation with local anesthesia. Laparoscopic placement requires general anesthesia. However, most patients are inpatients undergoing intensive bowel regimen therapy.

Summary of published evidence (Table 12) The percutaneous cecostomy tube is intended to replace the Malone appendicostomy for the treatment of defecation disorders with colonic irrigation. All of the published reports regarding the use of this device are retrospective and detail the indications, procedure, and outcomes in the pediatric population [120–124]. Most patients assessed by questionnaire reported improvement; there was minimal objective outcomes evaluation of this device and no long-term follow-up. There are no publications regarding the use of this device in adults.

Indications for this procedure Patients with moderate to severe fecal incontinence (CCFIS 8–20) who do not qualify for SNS or sphincter replacement strategies (e.g. anorectal malformations, spina bifida, Hirschsprung's disease, and other syndromes; neuromuscular incontinence/outlet obstruction).

Contraindications (relative/absolute) for this procedure

Absolute contraindications: Active infection, enterocutaneous fistulae, radiation enteropathy.
Relative contraindications: previous abdominal procedures, uncorrected coagulopathy, medical contraindications for the procedure.

Complications

- General: Pain, bleeding, infection.
- Specific: Cecal hematoma requiring open procedure; perforation of contiguous organ; fecal soilage; catheter dislodgement; catheter breakage; hypertrophic granulation tissue at insertion site; ventriculoperitoneal shunt infection.

Benefit/risk profile The overall risks of the procedure are moderate, while the efficacy in improving symptoms of fecal incontinence is moderate to high (GRADE recommendation: 2C).

CPT codes and physician reimbursement Placement of cecostomy tube insertion: 44300 open placement of enterostomy or cecostomy; 49442 percutaneous insertion of cecostomy (or other colonic) tube, under fluoroscopic guidance; and 49450 percutaneous replacement of cecostomy (or other colonic) tube, under fluoroscopic guidance

Summary on new technologies for fecal incontinence

Our review focused on a number of technologies that are currently discussed, and in some cases even marketed, for the treatment of fecal incontinence. The goal was to summarize the available evidence in the medical literature up to the present time in order to better define the role of such approaches. Intentionally, we did not address other more conventional treatment options such as sphincteroplasty, physical therapy, and pelvic floor rehabilitation, or dietary, pharmacological, and behavioral modifications. Unfortunately, there is no therapeutic panacea and there is not a single technique with perfect outcomes and no morbidities. The plethora of new and innovative therapies is attestation to the lack of universal success and the morbidity profile of each of the traditional and newer options.

Development of a treatment algorithm will have to be based on the severity of the incontinence, anatomical, and functional findings, but may also have to include financial considerations (cost/benefit analysis). While some of the treatments have not yet been FDA-approved and are without category 1 CPT codes (see "Comment on physician reimbursement" Appendix 3), a stepwise escalation along the various categories may appear reasonable and could look as follows:

(a) Severe morphological abnormality

Examples: Cloaca-like deformity after fourth-degree obstetrical injury, full-thickness rectal prolapse, recto-vaginal fistula, perineal trauma, etc.
Recommendation: Correct the defect first and initiate supportive conservative measures. Sphincter reconstruction may require non-stimulated muscle transfer (e.g. unilateral or bilateral graciloplasty or gluteoplasty).
Once the anatomy is restored, further options may be considered, including on a case-by-case basis (e.g. injectables, radiofrequency, SNS, or ABS).

(b) Sphincter defect (without previous repair), without major visible anatomical abnormality:

Examples: Fecal incontinence after vaginal delivery, post-surgical (hemorrhoidectomy, fistulotomy, sphincterotomy, etc.)
Recommendation: Consider sphincteroplasty if conservative measures failed. Alternatively, radiofrequency, injectables, SNS.

(c) Failed sphincter repair, without major visible anatomical abnormality:

Recommendations:
Minor fecal incontinence
(CCFIS 1–6): radiofrequency, injectables, PTNS.
Moderate fecal incontinence
(CCFIS 7–13): SNS, radiofrequency, injectables.
If failed: magnetic ring, ABS.
Severe fecal incontinence
(CCFIS 14–20): SNS, magnetic ring, ABS, or rarely non-stimulated graciloplasty (e.g. contraindication to implant).

(d) Failed surgical interventions, failed conservative measures, or contraindications to other interventions.

Recommendations: Consider trapdoor button or MACE procedure, or colostomy.

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Appendix 1

Table 13 The GRADE system—grading recommendations

	Description	Benefit vs. risk and burdens	Methodological quality of supporting evidence	Implications
1A	Strong recommendation, high-quality evidence	Benefits clearly outweigh risk and burdens or vice versa	RCTs without important limitations or overwhelming evidence from observational studies	Strong recommendation, can apply to most patients in most circumstances without reservation
1B	Strong recommendation, moderate-quality evidence	Benefits clearly outweigh risk and burdens or vice versa	RCTs with important limitations (inconsistent results, methodological flaws, indirect or imprecise) or exceptionally strong evidence from observational studies	Strong recommendation, can apply to most patients in most circumstances without reservation
1C	Strong recommendation, low- or very low-quality evidence	Benefits clearly outweigh risk and burdens or vice versa	Observational studies or case series	Strong recommendation but may change when higher quality evidence becomes available
2A	Weak recommendation, high-quality evidence	Benefits closely balanced with risks and burdens	RCTs without important limitations or overwhelming evidence from observational studies	Weak recommendation, best action may differ depending on circumstances or patients' or societal values
2B	Weak recommendations, moderate-quality evidence	Benefits closely balanced with risks and burdens	RCTs with important limitations (inconsistent results, methodological flaws, indirect or imprecise) or exceptionally strong evidence from observational studies	Weak recommendation, best action may differ depending on circumstances or patients' or societal values
2C	Weak recommendation, low- or very low-quality evidence	Uncertainty in the estimates of benefits, risks and burden; benefits, risk and burden may be closely balanced	Observational studies or case series	Very weak recommendations; other alternatives may be equally reasonable

Adapted from Guyatt et al. [125]

RCTs randomized controlled trials

Appendix 2

Table 14 Cleveland Clinic Fecal Incontinence Score [127]

Parameter	Frequency				
	Never	Rarely (<1/month)	Sometimes (<1/week but ≥1/month)	Usually (<1/day but ≥1/week)	Always (≥1/day)
Incontinence to solid stool	0	1	2	3	4
Incontinence to liquid/ loose stool	0	1	2	3	4
Incontinence to gas	0	1	2	3	4
Wears pad	0	1	2	3	4
Lifestyle alteration	0	1	2	3	4

Sum of the five parameters: perfect control = 0; complete incontinence = 20

Appendix 3

Comment on physician reimbursement

In the USA, physician reimbursement is defined by CPT codes (current procedural terminology). The individual codes and their Relative Value Unit (RVU) are defined by the Center for Medicare and Medicaid Services (CMS), a government agency. The American Medical Association as representation of the physicians reviews the CPT codes on an annual basis and submits changes and recommendations through its Relative Values Uptdates Committee (RUC).

Category III codes are tracking codes and CPT 46999 is used for unlisted procedure at the anus. These procedures either have not gone through the RUC process or are procedures that do not have enough 'scientific' support to become a category I code. Many times they are not recognized by 'third-party payers' and are considered experimental. In order to avoid cost burden to the practice, precertification and payment should always be acquired prior to the procedure being performed.

The process to 'attempt' to obtain reimbursement should include the following important components:

- Cover letter explaining the procedure, the amount of time to prepare the patient, the actual time to perform the procedure, and the immediate post-procedure care. Also of relevance is the site of the service (office, i.e. non-facility vs. a facility) and associated 'costs' of the procedure (medications, special equipment required, etc.).
- The operative note dictation has to be very specific about the details and duration of the procedure, the type of anesthesia utilized (e.g. local anesthesia, monitored anesthesia care (MAC), or general anesthesia).
- It would be helpful to include at least two similar codes that have almost equal pre-, intra-, and post-service time. Examples for the in-office injection procedures could include CPT codes 46500 (injection of sclerosing solution to hemorrhoids) and 46221 (ligation of hemorrhoids): pre-service time of 13/15 min, intra-service time 20/15 min, and post-service time of 13/15 min, respectively. Neither one of these codes would require anesthesia in the typical patient. Injection of dextranomer is similar to the abovementioned codes; its value falls around these two codes, at least in regards to work time and risk. The rationale could be based on a 50 % improvement in the absence of any relevant risks (in comparison to other treatment modalities for fecal incontinence).

Category III codes are tracking codes. When a procedure has a tracking code, the surgeon is required to utilize that code for billing, and it is considered billing fraud if it is not utilized.

Physician reimbursement for all CPT codes is determined by Center for Medicare Medicaid Services (CMS) and varies by geographic region. There is a complex formula that determines the total RVU value of the procedure (code). That total is multiplied by the current conversion factor set by CMS and Congress each year and is based on the Sustainable Growth Rate.

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