Multimodal Management of Traumatic Faecal Incontinence Focused on Sphincteroplasty: Long-term Outcomes From a Single Center Case Series

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Abstract

Background: The management of patients with fecal incontinence and an external anal sphincter (EAS) defect remains controversial.

Methods: We present a retrospective series of overlapping anal sphincteroplasties performed between 1985-2013 by a single surgeon supplemented by selective puborectalis plication and internal anal sphincter repair. Patients were clinically followed along with anorectal manometry, continence scoring (Cleveland Clinic Incontinence Score - CCS) and patient satisfaction scales. Patients with a suboptimal outcome were managed with combinations of biofeedback therapy, (BFT) peripheral tibial nerve stimulation (PTNS), sacral nerve stimulation (SNS) or repeat sphincteroplasty.

Results: There were 120 anterior sphincter repairs with 90 (75%) levatorplasties and 84 (70%) IAS repairs. Over a median follow-up of 120 months (range 60-173.7 months) there were significant improvements in the recorded CCIS values (90.8% with a preoperative CCIS > 15 vs. 2.5% postoperatively; $P < 0.001$). There were 42 patients who required ancillary treatment with 4 repeat sphincteroplasties, 35 patients undergoing biofeedback therapy, 10 patients treated with PTNS and 3 managed with SNS implants with an ultimate good functional outcome in 92.9% of cases. No difference was noted in ultimate functional outcome between those treated with sphincteroplasty alone compared with those who needed ancillary treatments (97.1% vs. 85.7%, respectively). Overall, 93.3% considered the outcome as either good or excellent.

Conclusions: Long-term functional outcomes of an overlapping sphincteroplasty are good. If the initial outcome is suboptimal, response to ancillary treatments remains good and patients are not compromised by a first-up uncomplicated sphincter repair.

Introduction

The traditional surgical management in patients presenting with fecal incontinence (FI) where there is an external anal sphincter (EAS) defect is an overlapping sphincteroplasty [1]. Although short- and medium-term functional outcomes after surgery are acceptable, some reports have shown that patients can anticipate a significant fall-off in the success of sphincter repair over a more prolonged follow-up [2–4]. Given the multifactorial nature of FI, the repair of a demonstrable sphincter defect remains valid [5]. There is considerable evidence that the success of sphincteroplasty, however, is dependent upon the level of experience of the surgeon [6] and the grade of the sphincter tear [7].

By comparison, sacral neuromodulation (SNM) was initially introduced into FI management for those patients with intact anal sphincters [8] but over time there has been an extension of its indications as a primary therapeutic alternative to include patients with an EAS defect [9–11]. In the management of such a patient, however, there have been those who have argued with equal conviction the pros and cons of SNM as a first-up treatment over delayed sphincter repair [5, 12]. For a benign condition such as FI, the subjective satisfaction reported by the patient remains an important indicator where it is accepted that

the standards judged for success between sphincteroplasty and SNM are not always strictly comparable [13] and where few treatments for incontinence will achieve a perfect result. Patients should also be advised regarding the known outcomes of salvage procedures when initial conservative therapy or individual surgical treatments have failed. This study analyzes the functional outcome of anal sphincteroplasty in a closely followed patient cohort managed by a single surgeon over a prolonged period with assessment of the clinical value of secondary complementary therapies if and when they were needed.

Patients And Methods

Ethical permission was obtained from the Hospital Clínico San Carlos (Madrid, Spain) local hospital Ethics Committee for the conduct of this retrospective analysis, and it was registered in Clinicaltrials.gov (NCT04727463).

All studies were performed in accordance with the approved guidelines and regulations of the institution. The requirement for informed consent was waived by Hospital Clínico San Carlos (Madrid, Spain) Review Board given the retrospective nature of the study.

Data were retrieved from a prospectively maintained database incorporating an unselected group of consecutive cases presenting with a history of severe fecal incontinence (FI) where there was an associated external anal sphincter (EAS) defect and who underwent an overlapping sphincteroplasty as definitive incontinence management. The study included all patients derived from a tertiary colorectal referral practice in a 900 bed University-affiliated hospital who were registered between January 1985 and December 2013 with all cases managed by a single surgeon (JCM) over this time period. All results are reported in accordance with the Preferred Reporting Of Case Series in Surgery (PROCESS) statement [14]. Cases were included with endosonographic evidence of an EAS defect who were considered for surgery after a failed period of conservative management which variably included dietary changes, constipating medication and biofeedback therapy (BFT).

Demographic data were collated (age, gender) along with the duration of symptoms, prior gynaecologic and/or proctologic surgery, previous obstetric history and the status of sexual activity. The severity of incontinence was assessed by the Cleveland Clinic Incontinence Score – CCIS [15] separating the score into 3 broad range categories (0–8; 9–15 and 16–20) similar to Rothbarth et al. [16]. All patients underwent 3D reconstructed anal endosonography (8838 probe B-K Herlev Denmark) and anorectal manometry (Synectics Medical, Stockholm) recording the maximal resting anal pressure (MRAP), the maximal squeeze pressure (MSP) and the high-pressure zone length (HPZ).

Surgical technique:

The policy was in general the performance of an overlapping EAS sphincteroplasty with puborectalis plication along with selective internal anal sphincter (IAS) imbrication where indicated. All patients underwent a mechanical bowel preparation with oral sodium phosphate (2 x 45 mL doses the day before

surgery) along with the administration of perioperative intravenous antibiotic prophylaxis (gentamicin plus metronidazole). Procedures were variably performed under regional or general anesthesia with patients catheterized and placed in the lithotomy position.

Briefly, the perineum was infiltrated with a 1: 200000 adrenaline-saline solution with a transverse incision made in the region of the perineal body and with sharp dissection (and protection) of the posterior vaginal wall, separating it from the anterior anorectum. The EAS was minimally mobilized in order to avoid denervation and/or devascularisation with an overlapping 2-layer sphincter repair using 2/0 Vicryl sutures. The puborectalis muscle was approximated towards the midline with usually 2 additional sutures. Any IAS defect anteriorly was closed using 4/0 interrupted Vicryl. In some cases the surgical wound was left either partially or completely open and allowed to heal by secondary intention. In those cases where there was destruction of the perineal body a Corman-style advancement perineoplasty was performed as a random pattern transposition flap [17]. This approach was used to reconstruct the perineal body and superficial perineal musculature as well as to restore the distal part of the rectovaginal septum by separating the anal and vaginal walls. Figure 1 shows the performance of the anterior sphincteroplasty and puborectalis plication. All procedures were performed without proximal diversion. The urinary catheter was left *in situ* for 48 hours with introduction of a regular diet at that time and the discretionary use of laxatives in the immediate postoperative period.

Those who were sexually active were advised to avoid sexual intercourse for the first 3 postoperative months. Patients were followed up regularly in the clinic to observe wound healing with ultimately 6 monthly assessments for the first 3 years and then annual checks thereafter. At each visit patients were clinically examined with determination of the CCIS. Anorectal manometry was conducted annually for the first 5 years with anal endosonography performed one year after surgery (unless otherwise indicated). Sonography was repeated in those with deterioration in their continence function. In those cases where there was a mild continence deterioration (≤ 4 CCIS points change) dietary means and constipating agents were used for control whereas in patients with a worse decline in function (> 5 CCIS points change), BFT was initially used. In those patients with disruption of the sphincter repair, a repeat sphincteroplasty was attempted usually after a 12-month period in the absence of any endosonographic evidence of local sepsis. In other circumstances and in the event that there was no improvement with BFT, either posterior tibial nerve stimulation (PTNS) or SNS was offered. At the conclusion of the study either face-to-face or telephone interviews were conducted assessing the final CCIS and a range of patient satisfaction surveys. With the study patients included from the 1980's before the introduction of some of the validated quality of life continence scales we recorded a combination of the Browning-Parks Scale [18] as Excellent, Good, Fair or Poor outcome along with a broad overall patient satisfaction as "completely satisfied", "somewhat satisfied" or "unsatisfied". An objective successful outcome was considered present when there had been a 50% or greater reduction in the CCIS after surgery, a parameter also used in the determination of successful outcomes following SNS [19]. Patients were also asked if given the same clinical circumstances they would undergo the same procedure.

STATISTICAL ANALYSIS

Analysis of data was performed using the SPSS Version 2.0 for Windows software (Chicago, IL). Qualitative variables are presented by frequency distribution. Quantitative variables are summarized by means ($\pm$ SD) or medians (plus interquartile range - IQR). Comparative pre- and postoperative paired data were assessed by the Student's t-test with ANOVA employed for repeated measures after Bonferroni correction. Preoperative manometric values were compared with the last available registered postoperative recordings. Categorical variables were compared with the χ^2 or Fisher's Exact test where appropriate with P values < 0.05 considered significant.

Results

Over the period of analysis, 113 women (94.2%) and 7 men (5.8%) underwent a total of 120 anal sphincter repairs (median overall age 59, range 16–84 years). Of the cohort, 56 (46.6%) were > 60 years of age and 17 (14.2%) > 70 years of age at the time of surgery. In presentation 97.5% complained of incontinence to solid stool, 99.2% to liquid stool and 100% had gaseous incontinence with 88% reporting urgency of defaecation and 65% regular soiling. The median duration of incontinence symptoms was 120 months (range 10–480 months). The cause of the sphincter injury was obstetric-related in 98 (81.6%) cases, following anal fistula surgery in 10 (8.3%), after other proctologic surgery (abscess drainage, internal anal sphincterotomy and haemorrhoidectomy) in 8 (6.6%) and with perineal trauma in 4 (3.3%) cases. Table 1 shows the clinical features and demographics of the operated cohort outlining their preoperative CCIS and the presence of concomitant pelvic floor disorders on clinical examination, as well as the surgical procedures performed to improve continence as well as to deal with ancillary anorectal pathology.

Table 1.– Demographic, preoperative and operative data for the whole group.

n = 120		
Age (years) *		59 (16–84)
Gender	Male	7 (6)
	Female	113 (94)
Duration of symptoms before surgery (Months) *		120 (10–480)
Baseline CCIS	Total*	18 (9–20)
	0–8	0 (0)
	9–15	11 (9.2)
	> 15	109 (90.8)
Preoperative Manometric Variables	RP (LNR: 65 mmHg) ‡	27 (20–35)
	MSP (LNR: 140 mmHg) ‡	50 (38–64)
	SL (cm) ‡	2.6 (2–3)
Endoanal Ultrasound (81)	EAS defect	81 (100)
	IAS defect	41 (50.6)
Previous Obstetric History ¥	Vaginal Deliveries	98 (86.7)
	Episiotomy (Range 1–5)	78 (69)
	Third-Fourth degree tear	41 (36.3)
Concomitant Pelvic Floor Disorders ¥	Rectocele	15 (13)
	Recto-Vaginal Fistula	10 (9)
	Pelvic floor descent	9 (8)

Data are expressed as number of patients and percentage.

* Median and range values.

‡ Median and Interquartile range (IQR).

¥ Data referred just to women.

CCIS: Cleveland Clinic Incontinence Score; RP: Resting pressure; MSP: Maximum squeeze pressure; SL: Sphincter length; LNR: Laboratory normal reference; EAS: External anal sphincter; IAS: Internal anal sphincter; OSph: Overlapping Sphincteroplasty; ALev: Anterior levatorplasty; TPFR: Total Pelvic Floor Repair.

			n = 120
		Rectal Prolapse	4 (3.5)
		Enterocele	3 (2.6)
Anal Incontinence Surgical Techniques	Apposition Sphincteroplasty		1 (0.83)
	Overlapping Sphincteroplasty (119 cases / 99.1%)	OSph Alone	12 (10)
		OSph + ALev	14 (11.6)
		OSph + IAS repair	16 (13.3)
		OSph + ALev + IAS repair	68 (56.6)
		OSph + TPFR	8 (6,6)
		OSph + Postanal Repair	1 (0.83)
Associated Pathologies Surgical Treatment	Rectocele		13 (10.8)
	Corman´s graft		8 (6.6)
	Recto-Vaginal Fistula		6 (5)
	Enterocele		2 (1.66)
	Hemorrhoidectomy		2 (1.66)
	Rectal Prolapse (Delorme)		1 (0.83)
	Rectal Villous Adenoma Removal		1 (0.83)
Data are expressed as number of patients and percentage.			
* Median and range values.			
‡ Median and Interquartile range (IQR).			
¥ Data referred just to women.			
CCIS: Cleveland Clinic Incontinence Score; RP: Resting pressure; MSP: Maximum squeeze pressure; SL: Sphincter length; LNR: Laboratory normal reference; EAS: External anal sphincter; IAS: Internal anal sphincter; OSph: Overlapping Sphincteroplasty; ALev: Anterior levatorplasty; TPFR: Total Pelvic Floor Repair.			

The EAS defect was anteriorly located in 105 (87.5%) cases, lateral in 11 (9.2%) and posterior in 4 (3.3%). The mean angle of separation of the muscle ends was 126° (range 90–180°; SD = 28°). An overlapping sphincteroplasty (OS) was performed in 119 cases (99%) with one direct apposition repair and with a concomitant levatorplasty in 90 (75%) of the patients. An IAS repair was performed in 84 (70%) cases. There was one reactionary haemorrhage requiring a return to the operating theatre with haemostasis and

resuturing. There were 24 (20%) wound infections all of which healed within 2–6 weeks by secondary intention. Of the cohort 105 (87.5%) were available for follow-up with 8 patients who died from unrelated events including one with chronic dementia who was unavailable for assessment along with 6 patients lost to follow-up. The median follow-up period was 120 months (range 60-173.7 months) with the shortest follow-up of 24 months and the longest at 372 months. The follow-up was > 5 years in 95 (79%) and > 10 years in 60 (50%) of the cases.

Table 2 shows the recorded CCIS values demonstrating significant improvement at all measured postoperative time periods when compared with the baseline ($P < 0.001$). This is shown graphically in Fig. 2. The baseline and last follow-up CCIS values were compared in 3 symptomatic severity groups. There were 90.8% with a preoperative CCIS > 15 compared with 2.5% postoperatively ($P < 0.001$). Preoperatively, there were 9.2% with a recorded CCIS between 9–15 compared with 6% of postoperative cases ($P < 0.001$) and 0% of cases with a preoperative CCIS < 8 compared with 91.5% of postoperative cases ($P < 0.001$).

Table 2.- Comparison of preoperative values of CCIS with that of the different postoperative periods.

Time	n	CCIS				95%-CI			p
		Preop.	SD	Postop.	SD	Mean Dif.	Inferior	Superior	
12 m	117	17.9	2.3	2.8	3.3	15.1	14.4	15.9	< 0.001
24 m	116	17.9	2.3	3	3.4	15	14.2	15.8	< 0.001
36 m	107	18	2.2	2.6	3	15.4	14.6	16.2	< 0.001
60 m	95	18	2.1	2.8	3	15.2	14.4	16	< 0.001
120 m	60	18.1	2.1	2.4	1.9	15.8	15.1	16.5	< 0.001
Last F-U	105	18	2.3	3.7	3.9	14.3	13.5	15.1	< 0.001

CCIS: Cleveland Clinic Incontinence Score; 95%-CI: 95% Confidence Interval; Preop: Preoperative; Postop: Postoperative; SD: Standard Deviation; Mean Dif: Mean Difference; m: months; Last F-U: Last Follow-up.

In the assessment at 5 years there was a significant improvement in the CCIS when compared with baseline for patients undergoing all types of repair (overlapping sphincteroplasty, $P = 0.05$; levatorplasty, $P = 0.006$ and IAS plication, $P = 0.009$). Of those undergoing a sphincteroplasty alone 78 (65%) reported good continence with the remaining 42 requiring ancillary treatment (Fig. 3). In this group, 4 patients underwent a repeat sphincteroplasty with a mean period between surgeries of 109 months (range 54–132 months) and with good functional outcome in 2 cases. Overall, an acceptable functional outcome was achieved in 92.9% of cases at final evaluation using a variable combination and sequence of BFT, SNS and PTNS therapies with 8 patients with an unsatisfactory outcome. There was no difference in the likelihood of a successful functional outcome between those undergoing a sphincteroplasty alone and

those who required ancillary treatments (97.1% vs. 85.7%, respectively). No significant differences were noted in the resting or squeeze manometric evaluations when compared with baseline, however, there was a significant increase in the mean HPZ length from 2.6–3.2 cm ($P = 0.032$).

Table 3 shows the results of a univariate analysis to determine which factors correlated with either the need for an ancillary treatment over and above surgery or with a good functional outcome adjudged as > a 50% improvement in the recorded CCIS. There were no specific clinical or operative factors identified for either category. Overall there were 112 (93.3%) of the patients who considered their outcome as either good or excellent on the Browning-Parks Scale, 114 (95%) satisfied on simple clinical assessment and 115 (96.2%) reporting a clear improvement over their subjective preoperative status. In all, 104/105 patients questioned would undergo the same procedure again under similar circumstances.

Table 3.- Univariate analysis of possible factors that could influence clinical results in terms of additional treatments necessity or global success at end follow-up time.

		Need of Additional Treatments			Satisfactory Results (> 50% Reduction in CCIS)		
		No n (%)	Yes n (%)	p	No n (%)	Yes n (%)	p
Age (years) *		53.9 (17)	56.4 (13)	0.4	56 (14)	53.8 (15)	0.67
Sex	Female (113)	73 (64.6)	40 (35.4)	0.71	8 (7.6)	97 (92.4)	0.45
	Male (7)	5 (71.4)	2 (28.6)		0 (0)	7 (100)	
Duration of FI (months) *		55.4	39.6	0.29	51.1	49.2	0.95
Location of Sphincter Tear	Anterior (104)	67 (64.4)	37 (35.6)	0.49	7 (7.2)	90 (92.8)	0.71
	Posterior or Lateral (16)	11 (68.8)	5 (31.3)		1 (6.7)	14 (93.3)	
Tear Grades*		126 (27)	126 (30)	0.93	115 (30)	128 (27)	0.27
IAS Repair	Yes (84)	54 (64.3)	30 (35.7)	0.8	4 (5.1)	74 (94.9)	0.21
	No (36)	24 (66.7)	12 (33.3)		4 (11.8)	30 (88.2)	
Levatorplasty	Yes (82)	55 (67.1)	27 (32.9)	0.48	6 (7.8)	71 (92.2)	0.69
	No (38)	23 (60.5)	15 (39.5)		2 (5.7)	33 (94.3)	
Associated Surgical Techniques	Yes (33)	25 (75.8)	8 (24,2)	0.13	2 (6.7)	28 (93.3)	0.9
	No (87)	53 (60.9)	34 (39.1)		6 (7.3)	76 (92.7)	
* Figures represent mean values and standard deviation; p value is for Student’s T test.							
CCIS: Cleveland Clinic Incontinence Score; M: Male; F: Female; FI: Fecal Incontinence; IAS: Internal Anal Sphincter.							

Discussion

The functional results of overlapping external anal sphincteroplasty performed by a single surgeon over a 28-year period for an unselected group of patients presenting with faecal incontinence (FI) are presented.

Overall there was an acceptable functional outcome in 92.2% of the 120 repairs with a median follow-up period of 120 months where 80% of cases were assessed for longer than 5 years. In the cohort, 35% of cases required ancillary postsurgical treatment for incontinence which variably included biofeedback therapy (BFT) and selective peripheral tibial nerve stimulation (PTNS) and sacral neuromodulation (SNS). Of this group overall there was a good reported functional outcome in 85.7% of cases.

A delayed anterior sphincter repair either alone or combined with puborectalis plication and with selected IAS repair still remains a good option for patients presenting with FI and an obstetric-related perineal injury. It is accepted that following any procedure to treat this condition that although continence may not be perfect (and where incontinence to flatus is almost impossible to manage by mechanical means), that patient satisfaction with the post-sphincteroplasty outcome may be a reasonable marker of the value of the procedure. In this regard, Oom et al. [20] in a medium-term follow-up in 172 cases where three-quarters were available for assessment only noted a moderate to good outcome in 60% of their patients which was, however, accompanied by a high satisfaction even when continence was far from perfect. This effect was noted because of a marked reduction in the frequency of incontinence episodes. In their group the outcomes were no better or worse after the 5-year follow-up period. Judged by these standards, an anterior sphincteroplasty can clearly result in an acceptable to excellent outcome over the longer term particularly when selected for younger patients (under 50 years of age) who are reluctant to undergo implantation of a permanent neurostimulator.

In the modern era, SNS is seen as a competitive alternative in those FI cases with a demonstrable EAS defect, but it should be remembered that broad use of neurostimulation may report suboptimal results [21] where there is a moderately high incidence of an initial lack of efficacy (or even an ultimate loss of efficacy in some cases). This technology may also be associated with the requirement for a range of procedural adjustments and revisions [22] including explantation in between 6–10% of cases [23]. In the study reported by Maeda et al. [21] of a cohort of patients undergoing SNS, the combined number of those with a suboptimal result and an adverse event remained high even though the ultimate functional outcome was good or acceptable. This study also reported an ultimate success rate of only 34.1% when secondary interventions became necessary.

Our numbers are too small to draw any conclusions regarding repeat sphincter repair and to recommend this as an option over SNS. Our results are also consistent with others demonstrating in successful cases a non-definitive improvement after surgery in measurable manometric parameters [24]. In these patients the effects of surgery may be to induce a functional anorectal stenosis with an alteration in anal compliance (or as in our cases) an increase in the functional length of the anal canal. The use of sphincter repair in experienced hands would appear to be a valid, low cost management option with durable long-term success [13, 25–29]. This approach would seem of particular value for example in young women presenting with FI who are reluctant earlier on in life to undergo neurostimulator implantation and who informed of the current results of either a future repeat sphincter repair or salvage SNS, are prepared to accept the predicted long-term outcome of a first-up sphincteroplasty. Our evidence would also support the fact that a sphincteroplasty does not clinically compromise the patient further

along and that ancillary treatments such as BFT can then be effective particularly as patients adapt to the newly configured anatomy of an overlap repair [25, 26].

The dreaded complication with sphincteroplasty is wound infection which leads to an overall worse functional outcome [25]. Most studies have reported postoperative wound sepsis in about one-third of cases [13, 26] with our results showing a lower comparative rate. The changing fate of sphincteroplasty in FI management also reflects the dynamic changes in its use amongst coloproctologists where there is somewhat misleading impression by some that the longer-term outcome of sphincteroplasty is generally poor whereas that of SNS is good. This has effectively led to a marked reduction in the number of sphincter repairs performed over the last decade with fewer surgeons available who have either the experience or volume of sphincter repair cases which can form effective comparisons with SNS. In this regard, a recent analysis by Xu et al. [23] conducted over a 6-year period between 2008–2014 showed a 4-fold increase in SNS use amongst coloproctologists in New York whilst there was a concomitant decrease by 25% in the use of sphincteroplasty. Importantly, this change in practice was reported during a period when there was an increase in the overall number of referred FI patients. Despite the value of a prolonged follow-up by a single dedicated surgeon, it is accepted that our study is limited by its small numbers and its retrospective design.

In summary, the long-term outcome in expert hands of overlapping sphincteroplasty plus puborectalis plication and selective IAS repair is good. Patients should be counseled about the fact that continence following a sphincter repair will not be perfect but they may be confident that an uncomplicated sphincteroplasty does not compromise their eventual functional outcome. The parameters for judging functional success after sphincter surgery appear harsher than those adopted for SNS, [30] but despite this caveat if further ancillary treatments (BFT, PTNS, or SNS) are needed postoperatively the ultimate outcome remains acceptable.

Declarations

Disclosures

Authors declare they have no conflict of interest. No funding was received.

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Author's contribution

- o Carlos Cerdán-Santacruz: study conception and design, acquisition of data, analysis and interpretation of data, drafting of manuscript, critical revision of manuscript.
- o Débora M Cerdán-Santacruz: study conception and design, acquisition of data, analysis and interpretation of data, critical revision of manuscript.
- o Lucía Milla-Collado: study conception and design, analysis and interpretation of data, critical revision of manuscript.
- o Antonio Ruiz de León: critical revision of manuscript.
- o Javier Cerdán-Miguel: acquisition of data, analysis and interpretation of data, drafting of manuscript, critical revision of manuscript.

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Figures

Figure 1

Detailed key technical points concerning an overlapping sphincteroplasty. Fig. 1a: Basal anal inspection. Scar tissue secondary to episiotomy and “smoothing” of anal margin should be noted. Fig. 1b: Dissection of both pubo-rectalis limbs and the ends of the external anal sphincter. Fig. 1c: Levatorplasty with interrupted sutures. Fig. 1d: Internal anal sphincter plication. Fig. 1e: Overlapping sphincteroplasty. Fig. 1f: Final result. The wound is left totally or partially open. No drains are used.

Figure 2

Mean values and 95%-CI of preoperative and each follow-up CCIS determination.

Figure 3

Flow-diagram of patients who needed additional treatments after initial sphincteroplasty. PTNS: Posterior tibial nerve stimulation; SNS: Sacral nerve stimulation.