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Original Article: Clinical Investigation

Troubleshooting of failed continence mechanisms in the ileocecal pouch: Operative technique and long-term results of the intussuscepted ileal nipple valve

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Abbreviations & Acronyms
CIC = clean intermittent catheterization
IIN = intussuscepted ileal nipple

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Objectives: To provide a detailed step-by-step operative technique, and to report on long-term functional and metabolic outcomes in secondary continence mechanisms in the form of secondary intussuscepted ileal nipple valves in revisional surgery of ileocecal pouches.

Methods: From May 1997 to May 2015, 18 female and 10 male patients suffering from dysfunctional primary continence mechanisms of their ileocecal pouch underwent revisonal surgery to create a secondary ileal nipple valve at our tertiary referral center. The average follow-up period was 65.4 months.

Results: After surgery, 24 patients were continent by day and night, and four patients showed minor incontinence with the use of a safety pad. The average frequency of clean intermittent catheterization decreased both during the day and at night. The diameter of the catheters used for clean intermittent catheterization increased significantly. No patient showed stomal stenosis, change of stool habits or metabolic situation in the follow-up period. Furthermore, the creation of the secondary ileal nipple valves did not affect the capacity of the reservoir. In the long-term follow up, two patients required the construction of a third continence mechanism, making for an overall success rate of 92% in the study group.

Conclusion: To our knowledge, this is the first study of long-term results after the creation of secondary ileal nipple valves. We provide evidence that the creation of a secondary ileal nipple valve is a safe and reliable procedure for continence restoration in ileocecal pouches with excellent functional and metabolic long-term outcomes.

Key words: continence mechanism, continent cutaneous urinary diversion, MAINZ-Pouch, pouch, revisional surgery.

Introduction

The ileocecal pouch – a low-pressure high-capacity reservoir – has certainly proved that it meets the demands of patients requiring a continent cutaneous urinary diversion, whatever their medical backgrounds.[1–3] To achieve continence, procedures, such as the intussuscepted ileal nipple valve (also referred to as the IIN) or the *in situ* embedded appendix, and their favorable functional outcomes have been described.[1,4–9] However, in some patients, these continence mechanisms fail for various reasons;[10] here, a comprehensive review by Ardelt *et al*. describes failure rates of primary continence mechanisms in up to 10% (for nipple valves) and 20% (for flap valves), with a considerable variation among the examined series, which they attribute to individual case load and surgical experience.[11]

Therefore, in complex cases and especially in the case of a failed appendix continence mechanism or a necrotic primary IIN, the creation of a secondary IIN might become necessary. Hence, the present article focuses in particular on illustrating the operative technique for the creation of an IIN as a secondary continence mechanism in ileocecal pouches, and reporting on the outcomes for 28 patients having received such treatment at our specialist hospital (University Medical Center of Würzburg, Würzburg, Germany).

The authors are well aware that the principles of secondary IIN creation for continent reservoirs of other than ileocecal origin have already been described and shown before – the interested reader is referred to these publications for further information.[1,12] However, the creation

of a secondary IIN in ileocecal pouches represents a special situation: as the ileocecal valve has to be re-functionalized during the procedure, and the fixation of the intussuscepted ileal nipple valve in itself, as well as in the ileocecal valve, differs significantly from existing publications, the authors felt it necessary to provide a detailed step-by-step operative technique summary and to report on long-term outcomes for their own patient population.

Methods

Patient group

From May 1997 to May 2015, 512 patients received an ileocecal pouch at our institution (out of a total pool of 1045 cystectomies). Of these, eight female and 10 male patients who lost the primary continence mechanism of their ileocecal pouch for several reasons, underwent revisional surgery through the creation of a secondary IIN at our institution making for a primary incidence of 3.5% of primary continence mechanism failure. Another 10 patients (nine female and one male), who had received their ileocecal pouch at other institutions, were referred for revisional surgery to our tertiary referral center, making for an overall patient group of 28 patients. The median age of these 28 patients requiring a secondary IIN was 55 years (range 8–79 years).

In 20 cases, the primary indication for creating a continent urinary diversion was a malignant pelvic disease, whereas eight patients suffered from benign conditions. A total of 17 patients received an *in situ* embedded appendix stoma as their primary continence mechanism. The remaining 10 patients had a primary IIN, and one patient a primary tapered ileal flap valve. The median follow-up period was 35 months (range 3–270 months). Table 1 describes the indications for revisional surgery, whereas Table 2 shows the indications for initial ileocecal pouch surgery. Table 3 describes the demographics of the examined patient group. Four classifications considering preoperative incontinence were defined: (i) no incontinence; (ii) low-grade incontinence (requiring 1 safety pad/24 h); (iii) intermediate incontinence (requiring 2–3 safety pads/24 h); and (iv) total incontinence (requiring >3 safety pads/24 h). The proportion of patients who suffered from comorbidities, such as diabetes or hypertension, were comparable to the general population.

Table 1 Indication for revisional surgery in the study participants

Indication for revisonal surgery	No. patients, *n* (%)
Incontinence and concomitant stomal stenosis	6 (21.4%)
Incontinence	11 (39.3%)
Recurrent stomal stenosis	2 (7.1%)
Recurrent stomal prolapse	1 (3.6%)
Traumatic false passage resulting in incontinence	1 (3.6%)
Parastomal hernia with incontinence	1 (3.6%)
Necrotic primary IIN	1 (17.6%)
Combination	5 (17.9%)
Incontinence with stomal prolapse	2 (7.1%)
Incontinence due to devastated appendiceal stoma resulting from traumatic false passage and stomal stenosis	3 (10.7%)

Table 2 Indication for surgery

Indication for surgery	No. patients, *n* (%)
Carcinoma	20 (71.4%)
Urothelial carcinoma	19 (67.9%)
Prostate cancer	1 (3.6%)
Benign conditions	8 (28.5%)
Interstitial cystitis	3 (10.7%)
Incontinence caused by spina bifida	1 (3.6%)
Incontinence caused by bladder exstrophy	1 (3.6%)
Incontinence caused by traumatic quadriplegia	1 (3.6%)
Incontinence caused by postnatal extirpation of a coccygeal teratoma	1 (3.6%)
Incontinence of unclear pathogenesis	1 (3.6%)

Table 3 Clinical demographics of study participants (*n* = 28)

Variable	*n* (%)
Sex	
Male, *n* (%)	10 (35.7%)
Female, *n* (%)	18 (64.3%)
Median age, years (range)	55 (8–79)
Median hospital stay, days (range)	24 (12–42)
Median BMI, kg/m^2 (range)	24.9 (18–39)
Median Karnovsky index (range)	100 (80–100)
Median follow up, months (range)	35 (3–270)

All the findings, data acquisition and processing in this study comply with the ethical standards laid down in the latest Declaration of Helsinki, as well as with the statutes of the ethics committee of the University of Würzburg regarding anonymized retrospective medical studies.

Statistical analysis

For statistical analysis, medians of normally distributed data were compared with the unpaired Student's *t*-test, whereas the χ^2-test was applied for intergroup comparison. Statistical calculations were carried out by using SPSS version 24 (IBM Corporation, Armonk, NY, USA). The significance level was set as $\alpha = 5\%$ and, thus, *P*-values <0.05 were considered statistically significant.

Operative technique step-by-step

Planning and preparation

Indications and preoperative examinations: The indication for a secondary continence mechanism in ileocecal pouches, as described here, is the irretrievably failed primary continence mechanism. It must be ensured that the patient has not lost a considerable amount of small intestine due to previous surgery to avoid postoperative short bowel syndrome and that other interventions (such as irradiation) have

not significantly damaged the small intestine. Required preoperative X-ray examinations include anterior–posterior and lateral pouchography with radiological visualization of the failed continence mechanism (e.g. with an olive-tipped syringe filled with contrast agent). Preoperative endoscopy of the ileocecal pouch confirms the failure of the continence mechanism, and evaluates capacity and possible pouch pathology (e.g. calculi).

Patient preparation: The day before surgery, the bowel is osmotically cleansed. During surgery, antibiotics (ampicillin/clavulanic acid and metronidazole) are administered and continued for 5–7 days postoperatively.

Postoperative care: Patients are mobilized immediately after surgery. Diet restoration is begun as soon as regular bowel movement is observed. Gravity drains are placed next to the ileocecal pouch and are removed as soon as the drainage is <50 mL/24 h. At discharge, the Foley catheter is left indwelling for continuous drainage for 14 days. The indwelling pouchofix catheter (a transcutaneous 10-Fr cystostomy catheter inserted in the cavity of the reservoir during the procedure) might be plugged during this period, if the Foley catheter is draining adequately. CIC is started after a pouchography has confirmed consistency and continence of the ileocecal pouch. The pouchofix catheter is removed when the patient carries out CIC confidently.

Procedure step-by-step

Step 0: The patient is placed supine with a Trendelenburg tilt. The surgical area to be sterilized and draped extends from the lower chest down to the upper thighs. A sterile 18-Fr Foley catheter is placed in the ileocecal pouch reservoir and blocked with 10-mL glycine solution. A midline incision is made from a point halfway between the umbilicus and xiphoid superiorly, and encircles the umbilicus to the left. Inferiorly, in most cases, it is sufficient to restrict the incision to a point halfway between the umbilicus and the symphysis pubis. It can, however, be extended to the symphysis pubis if severe adhesions in the pelvic area are encountered. In patients who have undergone previous midline incisions, the same skin incision should be used to avoid umbilical necrosis and to create a well-vascularized umbilical stoma. The small and large bowel are mobilized carefully to avoid serosal lesions and the need for bowel resection. The ileocecal pouch is identified, mobilized and freed from adhesions. Particular attention must be paid to the mesentery of the pouch, to retain its integrity. If the ureteric implantation sites are encountered, the ureters are secured with vessel loops.

Step 1: The dysfunctional outlet of the ileocecal pouch is then carefully dissected sharply from the (umbilical) stoma site and resected completely (Fig. 1a). The resulting defect is closed with a running absorbable suture line with 4/0 PDS. After that, the pouch is opened anti-mesenterically, and the ileocecal valve is identified and secured with a vessel loop or Foley catheter.

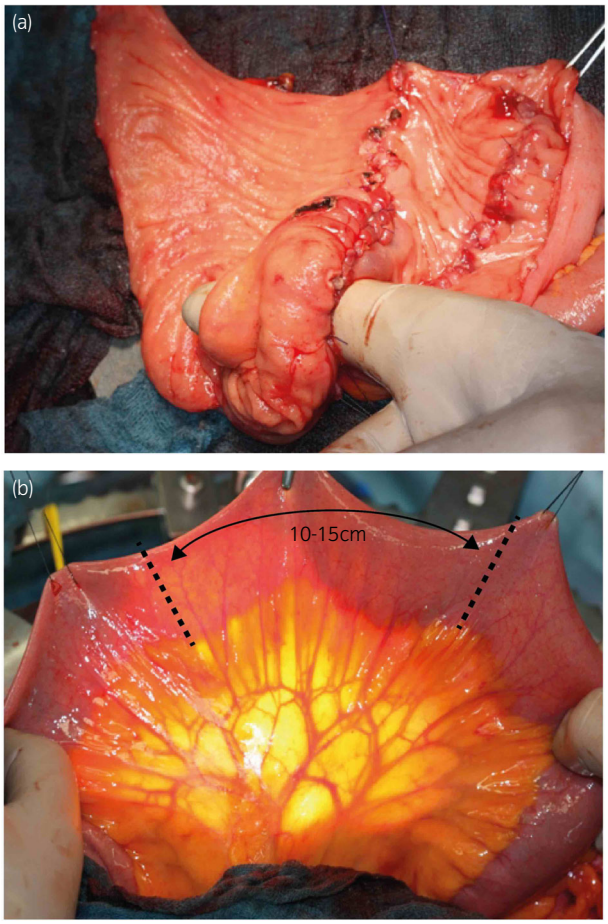

Fig. 1 (a) After opening of the reservoir and resection of the failed primary continence mechanism, the ileocecal valve is identified (in this case, the surgeons' finger is placed in the ileocecal valve for demonstration purposes). (b) After securing the ileocecal valve with a vessel loop or Foley catheter, a 10–15-cm small bowel loop for IIN creation is harvested. Diaphanoscopy facilitates the decision on resection margins based on mesenterial blood supply.

Step 2: Not every part of the small bowel is suitable for an IIN (Fig. 1b). Intestinal segments containing an ileoileal anastomosis are unsuitable, as are segments that have been severely damaged; for example, by radiation. The segment to be used as the secondary IIN should have a length of approximately 10–15 cm and a distance of at least 20 cm oral to the ileoascendostomy. The supplying mesentery should be long enough to reach the reservoir without tension. Meticulous closure of the mesenterial slit avoids postoperative ileus-related complications. Bowel continuity is restored with an ileoileal anastomosis as per surgeons' preference.

Step 3: Before invagination, a mesenterial window of approximately 5 cm is cleared in the middle of the resected ileal segment to ensure unimpaired perfusion of the ileal nipple after intussusception (Fig. 2). The following intussusception is generally carried out isoperistaltically. For this, two Allis clamps are inserted half way into the ileal segment at the aboral end and the ileal wall is grasped. After this, invagination is carried out by pulling on two previously

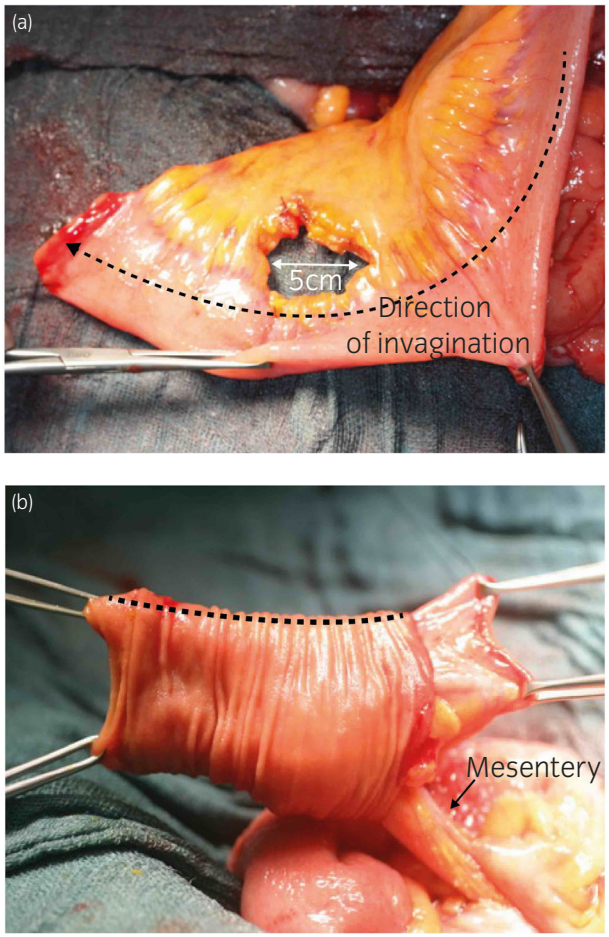

Fig. 2 (a) After harvesting the small bowel for IIN creation, a window of 5 cm in the middle of the mesentery is cleared (white arrow). The black dotted arrow indicates the direction of the upcoming isoperistaltic invagination. (b) Isoperistaltic intussusception is completed. The black arrow indicates the supplying mesentery of the IIN, whereas the dotted line shows the antimesenterial location for the first row of staples to be applied to fix and secure the invaginated ileum.

placed stay sutures at the aboral end. The intussusception is then fixed antimesenterially by using a single row of 4.8-mm titanium staples and a TA-55 autosuture device. To avoid wound healing disorders, wound infections and calculus formation, the tip of the IIN, which is in contact with urine, has to be free of staples. Here, removal of approximately five staples of the inner end of the TA-55 magazine before application is sufficient. Assuming that the mesentery is located at 6 o'clock, the first row of staples is applied directly antimesenterially at 12 o'clock.

Step 4: To pull the newly created IIN through the ileocecal valve, two to four Allis clamps are brought through the valve and the IIN is grasped (Fig. 3). With gentle tension, the IIN is pulled through the ileocecal valve. For fixation in the valve, two additional rows of staples are applied by bringing the TA55 through the nipple at the 3 and 9 o'clock positions. To ease this operative step, it is advisable to apply a longer "indicator" Allis clamp at the site of the first row of staples at 12 o'clock to spare the supplying mesentery at 6 o'clock. Through these additional two rows of staples, the IIN will be securely fixed in the ileocecal valve. Depending on the intraoperative situation (e.g. tilting of the IIN at the entry site through the ileocecal valve) several additional unresorbable interrupted sutures might be required to further fix the IIN securely in the ileocecal valve at the entry site into the reservoir.

Step 5: Ultimately, the pouch is closed by using a continuous 4/0 PDS suture (Fig. 4). To prevent gliding and/or dislocation of the IIN, several non-resorbable 4/0 stitches are used to fix the IIN to the outer wall of the reservoir. An intraoperative continence test is recommended to confirm a good outcome. By using a 18-Fr Foley catheter, the pouch is filled with 300 mL of 0.9% NaCl. After removing the catheter, continence can be tested in full view by gentle external pressure. For the anastomosis between the IIN and the umbilicus, we use Maxon 3/0 single stitches. A 10-Fr pouchostomy catheter is inserted transcutaneously as described before. The pouch is fixed with several non-dissolvable sutures to the abdominal wall. One 10-mm Jackson-Pratt drainage tube is inserted next to the pouch and a second one intra-abdominally.

Results

After creation of a secondary IIN, 24 patients were completely continent both during the day and at night (daytime was defined as the period from 07.00 to 19.00 hours, and night-time from 19.00–07.00 hours), and four patients showed minor incontinence requiring 1 safety pad/24 h. The average frequency of CIC decreased significantly both by day (from 3.77 to 2.16; $P \leq 0.01$) and at night (from 3.32 to 0.84; $P \leq 0.01$). After surgery, patients were also able to use catheters with a larger diameter for catheterization (average diameter 16-Fr preoperatively *vs* 18-Fr postoperatively; $P = 0.046$). None of the patients experienced stomal stenosis requiring stomal dilation or the need for surgical revision in the follow-up period. Also, no new-onset changes in stool habits, such as diarrhea or obstipation ($P = 0.86$), were observed in our patient group postoperatively. The capacity of the reservoir was not compromised by the creation of a secondary IIN (415 mL preoperatively *vs* 550 mL postoperatively, $P = 0.052$). These results are shown in Table 4.

During hospitalization, 14 patients did not experience any complication, whereas 12 patients experienced minor complications (Clavien–Dindo grade 1–2), such as the necessity of blood transfusion or cardiac arrhythmia. These complications are listed in Table 5. Complications necessitating reoperation (Clavien–Dindo grade 3–4) were observed in two patients: one secondary wound closure because of a wound healing disorder ,and one emergency re-laparotomy due to a Forrest 1b gastric bleeding. These results and general surgical considerations are shown in Table 6.

In the long term, four patients required revisional surgery on their secondary IIN due to nipple gliding: refixation in the ileocecal valve was carried out at an average of 62 months (range 10–174 months) after surgery in these patients. Ultimately, in two patients, accounting for 8% of our study group, the secondary IIN failed due to traumatic false passage in both cases. Here, the construction of a third continence

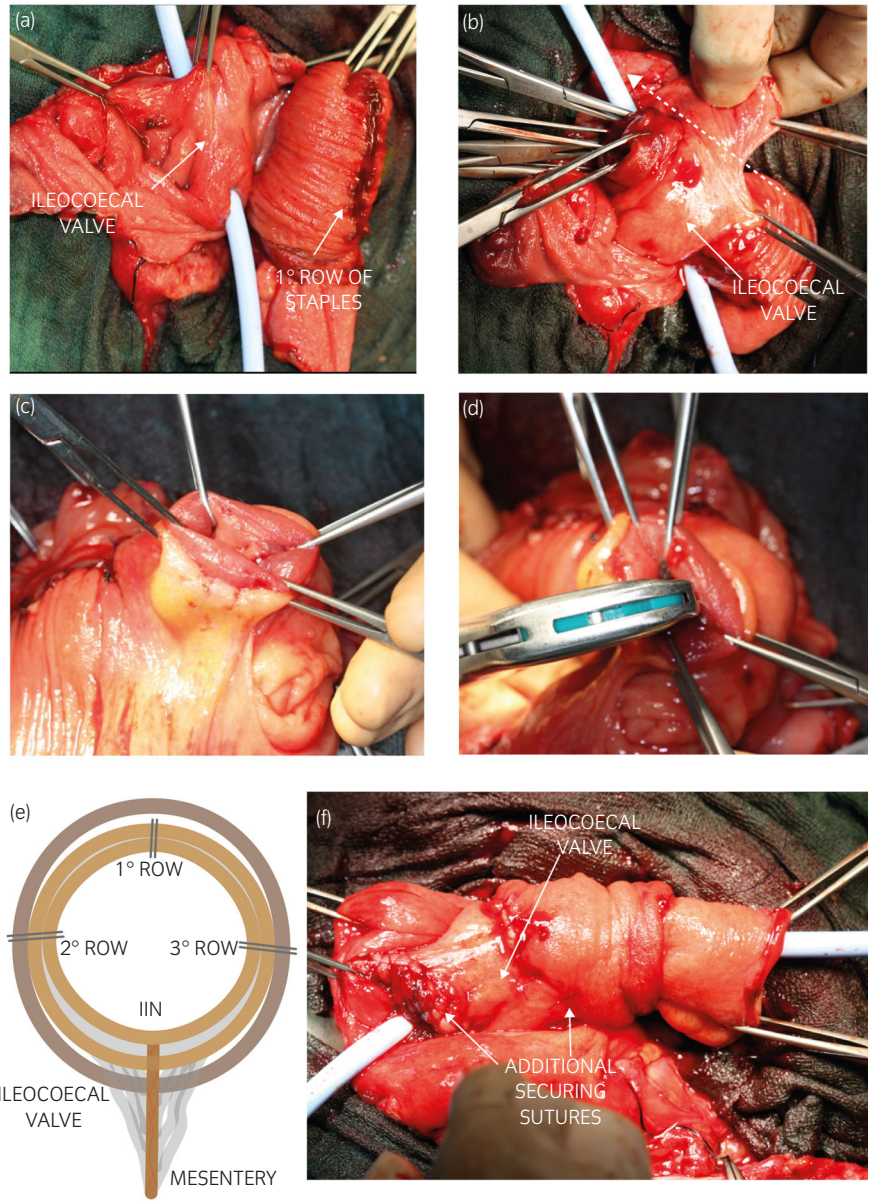

Fig. 3 (a) The invaginated nipple is fixed with a row of titanium staples using the TA-55 autosuture device at the antimesenterial side. The fixed IIN is then brought to the reservoir next to the ileocecal valve, which in this case is secured with a Foley catheter. (b) Using Allis clamps, the IIN is gently pulled through the ileocecal valve. The dotted arrow indicates the pull direction. (c) After pulling the IIN through the ileocecal valve, Allis clamps are used for temporary fixation until two additional rows of staples at the 3 and 9 o'clock positions secure the IIN in the ileocecal valve. (d) Using a TA-55 autosuture device, two additional rows of staples at the 3 and 9 o'clock positions are applied offset by 90° to the first row of staples, to retain the integrity of the supplying mesentery of the IIN. This can be eased by using a longer Allis clamp as a marker for the first row of staples or the site of the mesentery. (e) Schematic showing the placement of the three rows of staples to fixate IIN in itself and in the ileocecal valve relative to the supplying mesentery (Fig. 3a–d). (f) Fixation of the secondary IIN in the ileocecal valve is completed. Note the additional non-resorbable securing sutures proximal and distal to the ileocecal valve, which are facultative.

mechanism became necessary (one modified Monti outlet and one tapered ileal tube after 2 and 6 months, respectively). Importantly, even after these surgical re-re-interventions, no changes in stool habits, such as increased diarrhea or obstipation, were observed, making for an overall primary success rate of 92% in the present study group.

Discussion

This is one of the first studies reporting on the long-term outcomes after the secondary creation of an IIN for troubleshooting incontinence in ileocecal pouches. We were able to show that this procedure represents a safe and reliable technique for continence restoration in experienced hands, which is comparable to the outcomes of primary IIN construction in regard to continence and perioperative morbidity.[13] However, it has to be noted that this technique inevitably demands further bowel resection for the formation of the secondary continence mechanism. Therefore, during preoperative planning, the following facts have to be included in the surgeons' consideration: extensive preceding bowel resections or abdominal radiation therapy might foster short-bowel syndrome or bowel not suitable for reconstructive procedures with their respective early and late complications.

Intraoperatively, several pitfalls have to be addressed to ensure optimal outcomes. Being a revisional procedure, severe bowel adhesions intra-abdominally and especially in the small pelvis might be expected. Consequently, identifying the reservoir, and its supplying mesentery and separation from the stool-bearing intestine might be challenging in some cases. Filling the reservoir with approximately 200–300 mL saline solution through the indwelling Foley catheter can ease this preparative step. Next, utmost importance must be directed toward the decision as to which bowel segment is

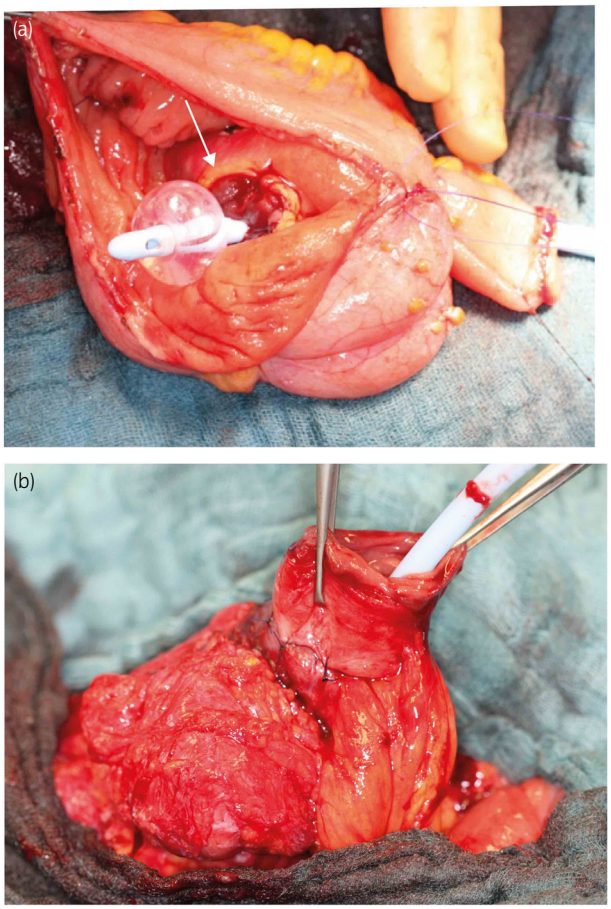

Fig. 4 (a) Frontal aspect of the reservoir with indwelling Foley catheter before closure. Note the fixated IIN in the ileocecal valve relative to the reservoir's cavity (white arrow). (b) After closure of the reservoir, circular non-resorbable sutures are used to fix the IIN to the outer reservoir's wall to prevent gliding of the secondary IIN.

Table 4 Functional outcomes

Variable	Preoperative	Postoperative	*P*-value
Defecation, *n* (%)			0.864
Normal	19 (67.8%)	19 (67.8%)	
Tendency towards constipation	1 (3.6%)	1 (3.6%)	
Tendency towards diarrhea	6 (21.4%)	6 (21.4%)	
CIC frequency by day (mean)	3.77	2.16	<0.01
CIC frequency by night (mean)	3.32	0.84	<0.01
Incontinence, *n* (%)			<0.01
None	2	24	
Low grade	4	4	
Intermediate	2	0	
Total	20	0	
Revisional surgery of secondary IIN, *n* (%)			
Refixation of secondary IIN	4 (14.3%)		
Requirement of a tertiary continence mechanism	2 (7.6%)		
Pouch capacity, mL (mean)	415	550	0.052
Catheter diameter, Fr (mean)	16	18	0.046
Necessity of stoma dilation (*n*)	6 (21.4%)	0 (0%)	0.014

Table 5 Minor complications

Complication	No. patients, *n* (%)
Blood transfusion	5 (17.9%)
Necessity of a gastric tube	2 (7.1%)
Tachyarrhythmia (drug treated)	1 (3.6%)
Episode of depression (drug treated)	1 (3.6)
Wound healing disorder treated with non-surgical treatment	2 (7.1%)
Puncture of a subcutaneous seroma	1 (3.6%)

Table 6 Surgical considerations of study participants (*n* = 28)

Variable	Values
Median operative time, min (range)	335 (135–620)
Median hospital stay, days (range)	24 (12–42)
Additional hernia, *n* (%)	5 (17.9%)
Previous abdominal surgery, *n* (%)	13 (46.4%)
Clavien–Dindo, *n* (%)	
0	14 (50%)
I	10 (35.7%)
II	2 (7.1%)
III	1 (3.6%)
IV	1 (3.6%)
V	0 (0%)

selected for IIN creation. In our experience, it is sufficient to limit adhesiolysis to a point at which a sufficient segment of ileum can be safely harvested. Here, it must be ensured that the supplying mesentery is long enough to reach the reservoir without tension. Second, especially with conglomerate adhesions of the intestine in the small pelvis, determining the direction of peristalsis of a selected ileal segment can be difficult. Here, in our experience, invagination in the direction of the anticipated peristaltic direction is sufficient in most cases.

The "worst case" scenarios intraoperatively are the inability to harvest suitable bowel for IIN creation or the situation that the ileocecal valve cannot be refunctionalized. Here, alternative surgical techniques that avoid using bowel segments – such as the serous-lined stapled pouch wall plication – have been described.[14]

Consequently, these should also be included in the armamentarium of every reconstructive surgeon to offer individual solutions for the often highly pretreated and complex cases with failed primary continence mechanisms. Here, it should be noted that long-term outcomes for these techniques are currently lacking and, therefore, they should be reserved for experienced, high-volume specialist hospitals.

Furthermore, close follow-up visits and proper education of patients receiving these kinds of revisional surgeries are vital for a good outcome, as a considerable amount of failed primary and secondary continence mechanisms are attributed to improper

handling and traumatic catheterization of the reservoirs. Regarding this, our work group established preoperative assessment tools of cognitive and functional disabilities correlating to postoperative constraints in self-catheterization.[15] We propose that these tools should also be validated in revisional procedures to potentially further improve patient outcomes.

In summary, a high level of surgical competence, creativity and flexibility are required in cases of revisional surgery for stomal insufficiency in continent cutaneous urinary diversion to ensure optimal outcomes and low rates of complications. Problems with catheterization can be avoided when paying utmost attention to proper surgical details at the time of continence mechanism creation. Stable and durable fixation of the continence mechanism, and a straight course of the continent outlet are essential to guarantee ease of catheterization. Even if the process of forming the secondary IIN is technically complex and many details have to be considered, the secondary IIN is an excellent solution in revisional surgery in experienced hands.

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Conflict of interest

None declared.

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