



## ORIGINAL ARTICLE

# Conversion of ileo-pouch anal anastomosis to continent ileostomy: strategic surgical considerations and outcome

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## Abstract

**Aim:** The aim was to evaluate surgical strategies for conversion of failed ileo-pouch anal anastomosis (IPAA) to continent ileostomy (CI), taking morbidity and overall outcome into account. The hypothesis was that complex conversions are equivalent to the primary construction of a CI at the time of proctocolectomy.

**Method:** This was a retrospective analysis of IPAA conversions acknowledging the underlying disease (inflammatory bowel disease [IBD] and non-IBD) and extent of pouch reconstruction (PR): type 1 (without PR), type 2 (partial PR), and type 3 (complete PR).

**Results:** Twenty-six patients (IBD,  $n = 16$ ; non-IBD,  $n = 10$ ) were converted (type 1,  $n = 13$ ; type 2,  $n = 7$ ; and type 3,  $n = 6$ ). 12/26 patients (46.2%) presented postoperative complications directly related to the conversion with scarification of two pouches. In a mean follow-up time of  $7.5 \pm 6.6$  years, 5/24 patients required revisional surgery. Of these, three required pouch excision. The cumulative probability of reoperation at the end of the second year increased to 21.7% and remained constant thereafter until the maximum follow-up time of 26 years. The total pouch loss rate was 19.2% (5/26), of which all occurred in the first 3 years. No statistically significant differences were found between the conversion types, complications or pouch survival. For all parameters, IBD patients performed slightly unfavourably. Due to the overall small number of respective patients, a differentiated investigation of IBD was not performed.

**Conclusion:** Complex conversion procedures (types 1 and 2) deliver comparable long-term results to new constructions (type 3), thereby limiting the loss of small bowel. IBD compromises outcome versus non-IBD.

## KEYWORDS

continent ileostomy, failed ileoanal pouch, kock pouch, pouch conversion

## INTRODUCTION

For patients requiring proctocolectomy, preservation of the normal defaecation pathway via ileo-pouch anal anastomosis (IPAA) has

become the preferred surgical option, offering very good functional results [1–3]. Notwithstanding the generally achievable high quality of life, the procedure has a cumulative failure rate of between 10% and 20% in a large series of 3707 patients from the Cleveland

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Clinic, Ohio, USA [2]. However, depending on both the underlying condition and the experience of the surgeon (case and hospital load) the cumulative rate may rise to 30% in smaller series [4]. Failures are mostly attributed to septic and functional complications of the pouch or pouch anal anastomosis, which may be resolved by a revision or redo procedure [5]. However, these procedures may also fail. Moreover, for patients with a compromised sphincter or a (pre-) malignant condition in the anorectal remnant, secondary reconstruction is not a reasonable option [6,7]. These conditions lead to sacrifice of the IPAA [8] and mostly patients are confronted with a conventional ileostomy (IS).

In selected cases, continent ileostomy (CI) deserves consideration and offers the advantage of complete control over faecal evacuation with a much improved quality of life compared to IS [9]. Let us recall that CI was initially described by Nils Kock [10] as an attractive alternative to IS as early as 1969. He demonstrated proof of principle for the prototype of the ileal pouch and as such his concept was the forerunner of IPAA [11]. This relationship constitutes the convertibility of IPAA into a Kock-pouch (KP) as the CI is also called when the original K-design is chosen for reservoir formation [11]. Starting in 1990, first casuistic reports on conversions of IPAA to CI were published, describing the addition of the nipple valve to the original J-pouch [12,13]. Since then two technical modifications were published in 1996 by our group [14]. Meanwhile reports on larger series have evolved; however, a considerable proportion of them describe completely new constructions and not true conversions [15,16]. However, in new constructions the opportunity of preserving the existing reservoir (and avoiding substantial loss of small bowel) is not respected [14,17]. We have systematically investigated the technical feasibility of preserving as much small intestine as possible and describe here our systematic approach to pouch conversions [18]. The aim of this study is to review the specific techniques in terms of their perioperative morbidity and long-term outcomes. The hypothesis is that individualized technical variants may reduce the proportion of pouch excisions versus pouch preservation and true conversions.

## PATIENTS AND METHODS

### Study design and statistics

This retrospective study includes all patients who were consecutively treated with conversion from IPAA to CI by one of the authors (KWE) between 1988 and 2015, with follow-up until 2020. Data from patient records were entered into a database in SPSS (statistics program of IBM™) for descriptive statistics. Cumulative probability rates were determined using a Kaplan–Meier analysis.

### Patient selection

All patients with IPAA failure and exclusion for redo-IPAA were informed and recruited. Pouch failure was defined by functional

### What does this paper add to the literature?

The significance of this paper is to provide evidence that reconstructive surgery versus complete continent ileostomy reconstruction spares small bowel without increasing complications or compromising functional outcome or overall continent ileostomy prognosis.

complications that could not be managed conservatively or by local surgery. Refractory severe pouchitis was excluded from any reconstructive surgery. Patients were diligently informed regarding the pros and cons of CI versus standard ileostomy as 'ultima ratio'. The decision was made by extensive counselling and informed consent.

### Special techniques

#### Construction of the nipple valve

As a rule, the nipple valve is formed from the afferent loop of the former J-pouch, which is then rotated 180° and re-anastomosed for bowel continuity. In the event of technical limitations (tension, scarring, desmoidal fibromatous and/or inflammatory changes) this part of the intestine may be maintained and a higher ileal or even jejunal loop is then transposed or interposed onto the former pouch outlet for nipple valve construction.

#### Reconstruction of the pouch

In general, the existing pouch is used as it is, but if the pouch is too small or if mobilization led to relevant injuries during the process, an augmentation is mandated in order to achieve a suitable reservoir size (volume). For this purpose, an isolated ileum or jejunum loop may be anastomosed side-to-side after longitudinal incision of the J-pouch instead of end-to-end resulting in an augmentation of a J- to an S-pouch. Only in the instance of significant loss of the pouch will a completely new pouch construction be seen as the procedure of choice. This new construction of the reservoir may derive from the neoterminal ileum or from a higher segment of the small intestine.

### Differentiated approaches to conversions

Based on the special techniques, three approaches were defined. These relate to the extent of pouch reconstruction (PR) and the origin of small bowel for the (re)construction.

The operative details including illustrative surgical drawings have recently been published elsewhere [18].

#### Type 1: J-pouch conversion without PR

- Type 1a: Nipple valve out of afferent loop
- Type 1b: Nipple valve out of higher ileum or jejunum

#### Type 2: J-pouch conversion with partial PR

- Type 2a: Nipple valve out of the afferent loop and augmentation of the pouch with a segment of proximal ileum or jejunum
- Type 2b: Nipple valve and pouch augmentation with a segment out of the proximal ileum or jejunum

#### Type 3: S-pouch construction as complete PR

- Type 3a: CI (S-pouch) fashioned from neoterminal ileum
- Type 3b: CI (S-pouch) fashioned from proximal ileum or jejunum and transposition to the distal position, interpositioning the previously distal bowel proximal to the CI

## Definition of complications

Complications were classified as intra-operative, early (<30 days) and/or delayed postoperative (<12 months) and long term. In expansion of the traditional 'early' postoperative definition of complications, for CI we suggest the addition of 'delayed postoperative' complications (<12 months), since due to the initial catheter-induced faecal diversion for several weeks and the slow incremental increase of reservoir function technical failure may remain occult during this time.

## Follow-up

All patients were invited to follow-up examinations, which were attended at irregular intervals. As a rule, patients actively contacted our institution in the event of problems. Since we wished to investigate the status of the patients who were not in touch, as of December 2020 a telephone interview was conducted by one of the authors (CD) in which all patients with CI were systematically contacted.

## RESULTS

### Patients and surgical approach

Twenty-six patients (13 men and 13 women) with a mean age of  $42.5 \pm 11.0$  years were included. The time since primary IPAA was  $4.9 \pm 5.4$  years. Underlying disease, conditions of previous IPAA constructions, conversion indications and conversion techniques are listed in Table 1. The diagnoses were divided into inflammatory (IBD,  $n = 16$ ), including ulcerative colitis (UC) and Crohn's disease (CD) strictly limited to the colorectum, and non-inflammatory (non-IBD,  $n = 10$ ) bowel disease including familial adenomatous polyposis

**TABLE 1** Patient demographics and surgical procedures

	n (%)
Patients	26 (100.0)
Male	13 (50.0)
Female	13 (50.0)
Underlying diseases	
Ulcerative colitis (UC)	14 (53.8)
Crohn's disease (CD)	2 (7.7)
Familial adenomatous polyposis (FAP)	8 (30.8)
Slow transit constipation (STC)	2 (7.7)
Previous construction of IPAA (J-pouch)	
Own series	6 (23.1)
Referred series	20 (76.9)
Time period of conversion	
1991–2010 (20 years)	11 (42.3)
2011–2015 (5 years)	15 (57.7)
Indication for conversion	
Incontinence	16 (61.5)
Evacuation difficulties	6 (23.1)
Anal or ano-vaginal fistula	2 (7.7)
Malignant transformation	2 (7.7)
Technique of conversion	
Type 1 (a/b = 7/6)	13 (50.0)
Type 2 (a/b = 2/5)	7 (26.9)
Type 3 (a/b = 4/2)	6 (23.1)
Age and time information, years	
Age at time of conversion ( $M \pm SD$ )	$42.5 \pm 11.0$
Median (range)	43.0 (21–63)
Interval IPAA to conversion ( $M \pm SD$ )	$4.9 \pm 5.4$
Median (range)	3.0 (0–23)

Abbreviation: IPAA, ileo-pouch anal anastomosis.

and slow transit constipation (STC). Most IPAA procedures were performed elsewhere ( $n = 20/26$ ). 11 of these patients (55.0%) had already received redo IPAA by other surgeons. Mostly, the indications for conversion were based on incontinence or unmanageable defaecation disorders. In two cases with UC cancer in the rectal remnant after IPAA, both uT2-uN0-M0, was diagnosed. Overall, in 50% of cases, a simple type 1 conversion was performed. The more complex type 2 and type 3 reconstructions were represented by approximately 25% respectively. Overall, subtypes 'a' and 'b' were equally distributed (Table 1).

### Early outcome

- Histological examination of resected specimens

Histological examination of the two anorectal cancer specimens confirmed the preoperatively assessed early and locally resectable

stage adhering to oncological principles. Moreover, both circumferential and oral resection margins were tumour-free. In 4/14 patients (28.6%) with the initial diagnosis of UC, clinical and/or histological features now identified underlying CD.

- Postoperative morbidity

In the absence of any intra-operative complications, 12 patients (46.2%) developed postoperative complications related to the IPAA conversion itself. These were equally distributed in type 1 ( $n = 7/13$ ) and type 2 ( $n = 4/7$ ) conversions, whereas in type 3 only one out of six patients required revisional surgery. The 12 affected patients had 16 individual complications that occurred at the nipple valve ( $n = 11$ ) or in the pouch or small intestine ( $n = 5$ ). In total, IBD patients ( $n = 10/16$ ) were threefold more affected with postoperative complications than non-IBD patients ( $n = 2/10$ ). Whilst two suture line leaks of the pouch led to emergency reoperation, all other revisions were performed semi-electively or electively and are included in our category of 'delayed' postoperative complications. These include nine fistulas of different origin (2× pouch, 1× small intestine, 6× nipple valve basis) and five mechanical nipple valve problems (2× prolapse, 2× nipple shortening and 1× nipple slippage). All complications were surgically repaired with preservation of function except in two cases with fistulas at the base of the valve. Interestingly, these occurred in two patients (one UC and one CD) with the indication for conversion being an irreparable anal or ano-vaginal fistula as an indicator for susceptibility towards developing fistulas aetiologically related to underlying disease. These patients lost their pouch in the postoperative course due to the inability of multiple revisions to definitively repair the fistula. The overall primary success rate after conversion and revision was thus 92.3% ( $n = 24/26$ ) corresponding to a primary pouch loss rate of 7.7% ( $n = 2/26$ ).

Complications related to the pelvic surgery were observed in six patients (23.1%). Of these, persistent sinus occurred in 4/11 patients with intersphincteric proctectomy (36.4%) and 2/15 developed abscesses after stapler or suture closure of the anus at its upper margin (13.3%). Since four of the six patients with sacro-pelvic complications concomitantly also experienced pouch conversion complications, the total number of patients with complications marginally increased from 12/26 (46.2%) to 14/26 (53.8%). There was no mortality in this series (0/26) (Table 2).

## Long-term outcome

All 24 patients with a successful conversion were available for long-term follow-up. Over a mean period of  $7.5 \pm 6.6$  years (median 6.0 years, range 0–26.0 years), five (20.8%) experienced a complication requiring revision, of whom two experienced a second and one an additional third revision. In this total of eight complications, three involved the nipple valve (2× fistula; 1× slippage) and five the pouch or afferent small intestine (2× fistula; 3× adenoma with high grade dysplasia).

All complications occurred within the first 2 years after conversion. Therefore, the cumulative probability of complications over the

**TABLE 2** Postoperative major complications

	n/n	%
All patients with complications	14/26	53.8
Patients with surgical complications of IPAA conversion	12/26	46.2
Relation to underlying disease		
IBD	10/16	62.5
Non-IBD	2/10	20.0 <sup>b</sup>
Relation to conversion type		
Type 1	7/13	53.8
Type 2	4/7	57.1
Type 3	1/6	16.7 <sup>c</sup>
Site and type of complication	16 <sup>a</sup>	100.0
Nipple valve	11	68.8
Fistula with incontinence	–6	
Mechanical problems	–5	
Pouch/small bowel	5	31.3
Fistula	–3	
Suture dehiscence	–2	
Patients with complications related to pelvic dissection	06 <sup>d</sup> /26	23.1
Persistent perineal sinus <sup>e</sup>	4/11	36.4
Supraleatory abscess <sup>f</sup>	2/15	13.3

Abbreviations: IBD, inflammatory bowel disease; IPAA, ileo-pouch anal anastomosis.

<sup>a</sup>Multiple mentions in 12 patients.

<sup>b</sup>n.s. ( $P = 0.087$ ).

<sup>c</sup>n.s. ( $P = 0.236$ ).

<sup>d</sup>4/6 complications in combination with complications related to IPAA conversion.

<sup>e</sup>After intersphincteric proctectomy.

<sup>f</sup>After closure of the upper anal canal.

long-term course was 21.7% in the first 2 years, remaining constant thereafter until year 10 (= last time to follow-up). Interestingly, the procedure-typical complications of the nipple valve were only responsible for a cumulative reoperation probability of 8.7%. By contrast, the disease-specific probability of complication of the pouch or ileum was significantly higher, reaching 13.5% (Figure 1).

## Pouch survival

A total of 5/8 long-term complications were surgically revised and led to complete restoration of functionality. Only in two patients with fistula formation at the pouch or the nipple valve and in one patient with nipple shortening did the attempted correction fail, so that these patients eventually lost the pouch and were converted to IS. Overall, the secondary (i.e., long-term) pouch failure rate was 11.5% ( $n = 3/26$ ). Together with the two primary pouch losses due

to postoperative complications, the total crude pouch loss rate was 19.2% (n = 5/26). 4/5 pouch losses involved patients with IBD (n = 4/16 corresponding to 25.5%), and one pouch loss was in non-IBD (n = 1/10, corresponding to 10.0%). This was a patient with STC who suffered from significant abdominal distention symptoms in addition to fistula-related incontinence.

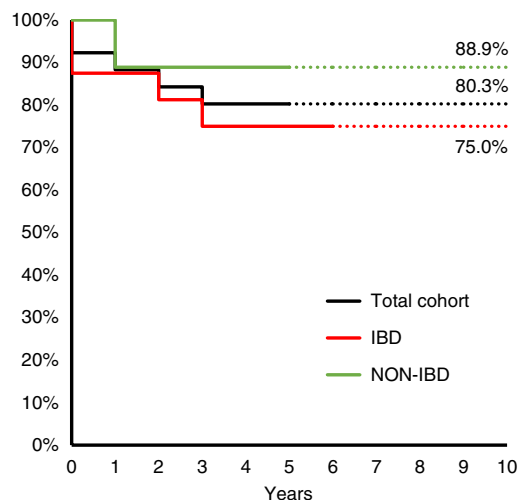
The calculation of the cumulative pouch survival rate revealed a correlation both with the underlying disease (Figure 2) and additionally with the conversion type (Figure 3). For both, the first three post-operative years were decisive for long-term pouch preservation. The probability of pouch survival in non-IBD decreased to 88.9% in the first year due to the pouch loss in the STC patient. For IBD patients, pouch survival rate decreased to 75% in the first 2 years due to four cases. Based on the conversion type, the probability of survival in type 3 (complete reconstruction) was calculated to be 100.0% for an observation period of 5 years. In contrast, for type 1 conversions the probability of pouch survival decreased to 76.9% in the third year and for type 2 conversions to 71.4% already in the first year. For both types the figures remained constant thereafter (see Figure 3).

## DISCUSSION

### Rationale for individualizing strategies

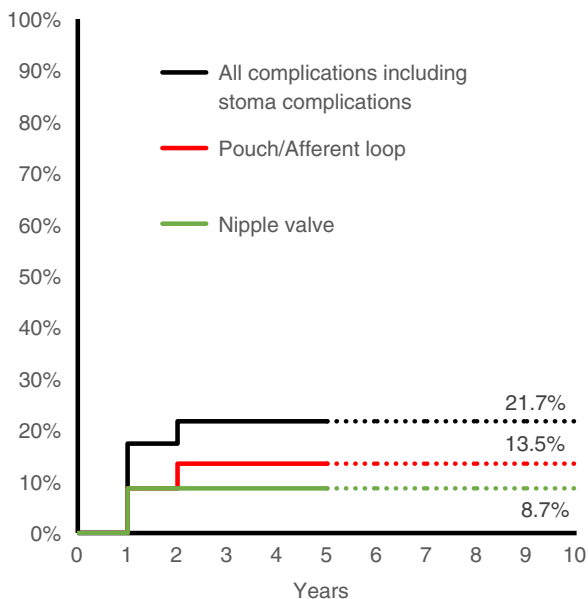
Conversion of a failed IPAA is today one of the most important indications for CI. In the literature, this specific subgroup of CI conversions is frequently jointly published with primary CI constructions

[19]. Overall, and as an indicator for the need to address separately, eight studies are devoted exclusively to the IPAA to CI conversion topic (see Table 3). In historical sequence, after first casuistic reports with a 'true' conversion, some dedicated centres published small series, but usually these included more new CI constructions than pouch-conserving conversions.



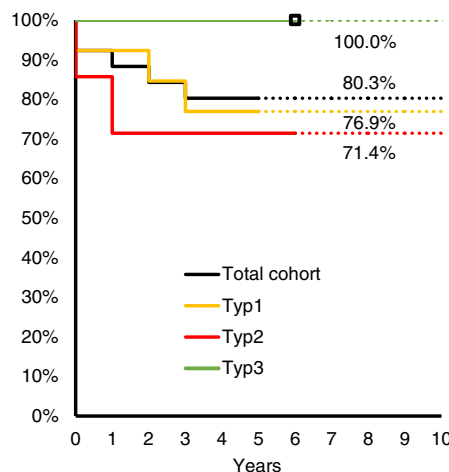
Years	0	1	2	3	4	5	6	7	8	9	10	
Pts (n)	26	22	21	20	20	19	12	9	8	6	6	Total cohort
Pts (n)	16	14	13	12	12	12	8	6	5	4	4	IBD
Pts (n)	10	8	8	8	8	7	4	3	3	2	2	NON-IBD

FIGURE 2 Cumulative probability of pouch survival as related to the underlying disease



Years	0	1	2	3	4	5	6	7	8	9	10
Pts (n)	24	19	18	18	18	17	10	7	6	4	4

FIGURE 1 Cumulative probability of a first revision surgery with respect to localization dysfunction



Years	0	1	2	3	4	5	6	7	8	9	10	
Pts (n)	26	22	21	20	20	19	12	9	8	6	6	Total cohort
Pts (n)	13	12	11	10	10	9	7	5	5	4	4	Typ1
Pts (n)	7	5	5	5	5	5	3	3	2	1	1	Typ2
Pts (n)	6	5	5	5	5	5	2	1	1	1	1	Typ3

FIGURE 3 Cumulative probability of pouch survival as related to the conversion type

In addition to the restoration of continence, the preservation of physiological reserves through extensive preservation of the small intestine deserves more attention [16,17,20]. Some of these patients are on the verge of developing intestinal failure. Therefore, it seems consistent to search for technical variants that bridge the gap between 'simple' conversion and complete reconstruction so that more patients may optimally benefit from the procedure. This requirement is especially true for the not inconsiderable number of patients who have previously received a redo IPAA. While the details of the different surgical techniques according to the three-part classification will be presented in detail elsewhere [9], a clinical benefit-risk consideration will be discussed here.

### Technical advantages of the 'b' variants of the conversion types

From a technical point of view, if conversion is intended the J-pouch should be preserved and dissected as carefully and atraumatically as possible [17,21]. Minor unavoidable damage can be repaired in a pouch-preserving manner [22]. However, sometimes it cannot be avoided that parts of the J-pouch are sacrificed due to scarring and chronic inflammatory and fibrodesmoidal changes and therefore an augmentation of the reservoir is required. In most of these cases no passage obstruction existed preoperatively; therefore obstruction will not become functionally relevant postoperatively. Singular or multiple bowel transpositions in the sense of the 'b' variants of the three conversion types are then suitable to avoid unnecessary bowel loss. The fact that more proximal ileal or jejunal loops are rarely involved after previous IPAA construction or IBD offers opportunities, apart from the fact that these bowel segments are mostly spared from disease! The possibility of using transposed jejunum for pouch construction has previously been described by Barnett in CD patients [23].

### Surgical safety considerations

Overall in the available literature (Table 3) the average rate of complications is 35.2% (31.3%–54.5%). However, the interpretation of the present study in comparison to these results is difficult. First, the definition period for postoperative complications has here been extended to 12 months for reasons outlined in our previous report concerning primary CI constructions [9]. On the other hand, septic complications in the sacral cavity after excision of an IPAA are generally very common and are not necessarily related to subsequent reconstruction [24]. This study makes it clear that these complications cannot generally be avoided if the sphincter is preserved instead of performing proctectomy, as is our preference.

However, for the assessment of the procedural safety of conversion surgery, its immediate postoperative complications are of primary importance [16]. In this study, 'true' conversions (types 1 and 2) were indeed shown to be more prone to complications than new constructions (type 3). Nevertheless, the statement of Wasmuth et al. is not

contradicted in that the surgical burden of a conversion of the IPAA is not higher than would be expected for a new construction of a CI in general [21]. Even more, complications are mostly treated electively with a high success rate. In concordance with most authors, virtually no surgical mortality occurred and the primary pouch loss rate remains low even with complex reconstructions [16,17,20].

### Clinical features of conversion surgery

Surgical complications in CI are predominantly attributed to insufficient durability of the nipple valve [25]. This study addresses complications of the underlying causative disease mandating proctocolectomy and the short- and long-term rate of success of conversions, based on the different bowel segments utilized. Regarding IBD, it should be kept in mind that the differential of successful repair in IBD patients is basically comparable in IPAA and CI [26,27]. The knowledge on CI and CD has increased considerably in recent years. A study from Cleveland, Ohio, USA, still states a higher revision rate in CD compared to UC after CI construction diagnosis between UC and CD remains uncertain and may change over time. Therefore, in this study, UC and CD limited to the colorectum are jointly analysed. It is possible that the primary under-recognition of CD is a partial cause of the failure of some IPAAAs [26]. A study from Cleveland/USA still states a higher revision rate in CD compared to UC after CI construction [28]. In an even more recent study from Sweden, however, no significant differences between UC and CD were identified [29]. Based on our experience we concur that CD limited to the colorectum should not be a contraindication to conversion, however, basing this on critical and individual patient selection [28]. It is possible that CI outcomes in IBD will generally improve in the future, taking technical improvements and the prospect of new and still evolving ever more customized drugs into account [30].

Two circumstances deserve special attention in the context of pouch conversions.

1. Pouchitis: Pouchitis is generally expected to occur with equal frequency and similar morphological phenotypes in IPAA and CI [31]. With this in mind, severe pre-existing pouchitis will always be a contraindication to conversion. In contrast, mild pouchitis should not preclude conversion because its leading symptom, the deterioration of continence, resolves after conversion due to restoration of nipple valve competence.
2. Anorectal cancer: It does not seem justified to exclude IPAA conversion in the event of an anorectal or anastomotic cancer diagnosis. In both reported cases here, malignant spread into the pouch was not histologically detectable and the further course after conversion remained free of locoregional recurrences and distant metastases. Whilst other authors in comparable cases always sacrifice the pouch in the course of exstirpation [7], to our knowledge this is the first case description of successful cancer-free pouch preservation in patients affected at this site.

**TABLE 3** IPAA conversions: review of the literature and comparison with this study

Number	First author (year) [ref.]	Procedure			Postoperative	Long-term outcome		
		Patients <i>n</i>	Conversion <i>n</i>	New CI <i>n</i>	Complications <i>n</i>	Repair operation <i>n</i>	Success <i>n</i>	Failure <i>n</i>
1	Kusunoki (1990) [11]	1	1	0	0	0	1	0
2	Hultén (1992) [12]	5	5	0	0	1	4	1
3	Ecker (1996) [13,14]	5	5	0	0	1	4	1
4	Behrens (1999) <sup>a</sup> [14,15]	42	4	38	n.s.	14	40	2
5	Karoui (2004) [24]	7	7	0	n.s.	6	2	5
6	Börjesson (2004) <sup>b</sup> [16,17]	13 <sup>b</sup>	12	1	5 (38.5)	8	10	3
7	Lian (2009) [15,16]	64	16	48	20 (31.3%)	29	61	3
8	Wasmuth (2009) [20,27]	11	7	4	6 (54.5%)	4	9	2
	Total in literature	143 <sup>d</sup>	52 (36.4%)	91 (63.6%)	31/88 (35.2%)	63 (44.1%)	127 (88.8%)	16 (11.2%)
9	This study <sup>c</sup>	26	20 (76.9%)	6 (23.1%)	14 (53.8%)	5 (19.2%)	21 (80.8%)	5 (19.2%)

Abbreviations: CI, continent ileostomy; IPAA, ileo-pouch anal anastomosis; n.s., not sufficiently stated.

<sup>a</sup>Five US centres including exclusively the modification of Barnett [23].

<sup>b</sup>Including five patients of Hultén.

<sup>c</sup>Including five patients of Ecker.

<sup>d</sup>Exclusive of five of Hultén.

## STRENGTHS AND WEAKNESSES OF THE STUDY

To date, the present study is the largest series of true conversions from IPAA to CI. We here propose a prospective validation that will contribute to more accurate prediction of success or failure in patient selection. As so often, the major weakness results from the retrospective study design and the fact that quality of life measurement was not performed.

## CONCLUSION

Classification into three types of conversion according to the extent of pouch salvage demonstrates a useful basis for bowel-sparing conversion of IPAA and prospective validation. Preserving as much of the small bowel as possible is particularly important in the cohort of patients after a primary IPAA and not infrequently a secondary IPAA. The underlying disease as demonstrated in this series may or may not be a limiting factor, but definitely always must be preservation of the small bowel and a pre-existing reservoir an aim of the conversion. Outcome is not compromised by this strategy, as demonstrated in this unique patient cohort.

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## CONFLICT OF INTEREST

There is no conflict of interest for any author.

## AUTHOR CONTRIBUTIONS

Karl-Wilhelm Ecker: all four criteria of ICMJE, especially taking primary responsibility for the investigation; writing the first draft of the manuscript; managing the communication with the journal. Christian Dinh: all four criteria of ICMJE, especially conducting the investigation and preparing the manuscript. Nils K.J. Ecker: all four criteria of ICMJE, especially supervising the statistical calculations and preparing the manuscript. Gabriela Möslin: all four criteria of ICMJE, especially critically revising the manuscript for important intellectual content. All authors commented on previous versions of the manuscript, read and approved the final manuscript.

## ETHICAL APPROVAL

The study was approved by the Ethics Committee of the Medical Association of Saarland, Germany (ID no. 24/15), on 4 February 2015 and the Ethics Committee of the University of Rostock, Germany (registration number A 2015–0040), on 7 April 2015.

## PATIENT CONSENT STATEMENT

Before applying for the ethics approval, verbal consent of the patients was obtained to analyse their medical records.

## DATA AVAILABILITY STATEMENT

All data are available electronically from the first author.

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