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Short-term morbidity and quality of life from a randomized clinical trial of close rectal dissection and total mesorectal excision in ileal pouch–anal anastomosis

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Background: Posterior rectal dissection during ileal pouch–anal anastomosis (IPAA) can be performed in the total mesorectal excision (TME) or close rectal dissection (CRD) plane. The aim of this study was to compare morbidity and quality of life (QoL) in patients having TME or CRD during proctectomy followed by IPAA for benign disease.

Methods: In this randomized clinical trial, patients undergoing IPAA were allocated to TME or CRD. Thirty-day morbidity was determined and QoL assessed using Short Form 36, GIQLI (GastroIntestinal Quality of Life Index) and COREFO (COloRECTal Functional Outcome) questionnaires. The primary outcome (pouch compliance) of the trial is to be reported separately.

Results: Fifty-nine patients were included, 28 in the CRD and 31 in the TME group. Baseline data were similar, except for more previous abdominal surgery in the TME group. Operating time was longer for patients having CRD (195 min *versus* 166 min for TME; $P = 0.008$). More patients in the TME group had a primary defunctioning ileostomy (7 of 31 *versus* 1 of 28 for CRD; $P = 0.055$). Severe complications occurred more frequently in the TME group (10 of 31 *versus* 2 of 28 for CRD). QoL was better in the CRD group for several subscales of the questionnaires measured at 1, 3 and 6 months after surgery. At 12 months, QoL was similar in the two groups for all subscales.

Conclusion: CRD led to a lower severe complication rate and better short-term QoL than wide TME.

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Introduction

Restorative proctocolectomy is the procedure of choice for patients with refractory ulcerative colitis and polyposis coli. It can be performed as a one- or two-stage procedure, with or without defunctioning of the ileoanal anastomosis. Both the rectal dissection and the pelvic reservoir reconstruction give rise to short- and long-term morbidity, such as anastomotic leakage, and pouch and sexual dysfunction^{1–3}.

Different techniques can be used to dissect the rectum. Most surgeons use a total mesorectal excision (TME) plane, taking advantage of the avascular plane with easy and bloodless dissection. The disadvantage of this technique is the chance of damaging the autonomic nerves, which lie immediately anterolateral from the mesorectal fascia. An alternative technique is close rectal dissection

(CRD), in which the rectum is dissected through the non-anatomical perimuscular plane close to the muscularis propria of the rectum. CRD is an elaborate approach owing to the non-anatomical dissection⁴. Nowadays, the technique has become less elaborate as a result of the use of vessel-sealing devices⁵. In the Academic Medical Centre, Amsterdam, The Netherlands, the TME technique is applied in restorative proctocolectomy, with the exception that the anterolateral mesorectum is preserved, thereby keeping a distance from the nerves. Sexual dysfunction in men has therefore been a negligible problem⁶.

The primary outcome of this randomized clinical trial was to compare pouch compliance between CRD and TME. In the present study, preliminary data on short-term morbidity and quality of life (QoL) up to 1 year are reported.

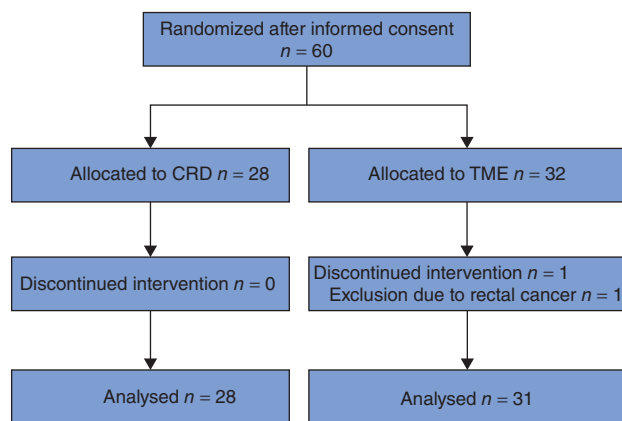


Fig. 1 Flow diagram for the study. CRD, close rectal dissection; TME, total mesorectal excision

Table 1 Baseline characteristics

	CRD (n = 28)	TME (n = 31)*
Age (years)*	35.3(13.3)	34.9(9.0)
Sex ratio (M : F)	19 : 9	19 : 12
Body mass index (kg/m ²)*†	23.9(3.3)	24.5(3.8)
Smoker	5	7
Previous midline laparotomy	6	16
Indication for IPAA		
FAP	4	2
Ulcerative colitis	23	27
IBD-U	1	2
Anti-TNF use < 12 weeks preop.	0	1
Perioperative steroid use > 20 mg/day	5	1

*Values are mean(s.d.). †Data missing for one patient. CRD, close rectal dissection; TME, total mesorectal excision; IPAA, ileal pouch–anal anastomosis; FAP, familial adenomatous polyposis; IBD-U, inflammatory bowel disease – unspecified; TNF, tumour necrosis factor.

Methods

This single-blind randomized clinical trial was performed in a university hospital (Academic Medical Centre, Amsterdam). Patients aged over 18 years with American Society of Anesthesiologists fitness grade I or II, scheduled for single- or multiple-stage ileal pouch–anal anastomosis (IPAA) in an elective setting, were eligible for the study. Patients were included between June 2007 and August 2011. After giving written informed consent, patients were randomized in a 1 : 1 ratio using sealed, opaque, sequentially numbered envelopes by means of block randomization (block sizes of 6 and 8). All patients were blinded for the type of dissection during the entire study period. Medical staff were not blinded.

The study protocol was approved by the Institutional Review Board of the Academic Medical Centre, and the trial and protocol summary were registered

Table 2 Characteristics of the procedure

	CRD (n = 28)	TME (n = 31)	P‡
Stage of procedure			
Primary restorative proctocolectomy	13	7	
CP after IRA	1	1	
CP after emergency colectomy	14	23	
Incision type			
Pfannenstiel	20	12	
Midline	8	19	
Operating time (min)*			
Overall	195 (169–292)	166 (146–185)	0.008
Primary restorative proctocolectomy	293 (212–308)	264 (146–301)	0.311
CP	170 (153–199)	162 (147–175)	0.155
Defunctioning ileostomy			
Primary	1	7	0.055#
Secondary at ≤ 30 days†	1	2	
Secondary at > 30 days‡	1	3	
Time of ileostomy reversal (months)			
3		3	
6	1	3	
12	1	2	
No reversal or > 12 months§	1	4	

*Values are median (i.q.r.). †Defunctioning ileostomy 8, 14 and 29 days after surgery; ‡defunctioning ileostomy 140, 155, 193 and 305 days after surgery. §In three patients the ileostomy was not reversed owing to persisting high defaecation frequency in one patient in the CRD group, and persisting active proctitis in one patient and anastomotic leakage in another (both in the TME group). CRD, close rectal dissection; TME, total mesorectal excision; CP, completion proctectomy; IRA, ileorectal anastomosis. ‖Mann–Whitney *U* test, except #Fisher's exact test.

(International Standard Randomised Controlled Trials Number (ISRCTN) 35140084). The protocol includes long-term pouch volume, distensibility and continence measurements by barostat. These results will be published at a later stage. Reporting of the data conforms to the Consolidated Standards of Reporting Trials (CONSORT) guidelines.

Total mesorectal excision *versus* close rectal dissection

All single-stage procedures were done hand-assisted with pouch creation via a Pfannenstiel incision. In two-stage procedures, a midline or Pfannenstiel incision was used, depending on the approach (open or laparoscopic) of the emergency colectomy. A 10-cm J pouch was created with a double-stapled ileoanal anastomosis. A defunctioning ileostomy was created selectively. All procedures were performed by three experienced colorectal surgeons.

In both TME and CRD for benign disease, anterior rectal dissection is performed on the outer muscle layer of the distal rectum. The difference is in posterior rectal

Table 3 Thirty-day morbidity and hospital stay

	CRD (n = 28)	TME (n = 31)	P ^{¶¶}
Clavien–Dindo classification			0.027
None	20	19	
Grade I	4	1	
Grade II	2	1	
Grade IIIA	0	5 [†]	
Grade IIIB	2 [‡]	5 [§]	
Grade IV–V	0	0	
Anastomotic leak	2	6	0.259
Length of hospital stay (days)*			
Primary stay	8 (7–10)	7 (6–9)	0.137 [#]
Total stay	9 (7–11)	9 (7–12)	0.988 [#]
Readmission < 30 days after discharge	3	12	0.018 ^{**}

*Values are median (i.q.r.). [†]Percutaneous drainage of an abscess (4 patients), anastomotic bleed requiring endoscopy of the pouch (1). [‡]Presacral abscess with a small anastomotic defect treated by Endo-SPONGE[®] (B. Braun Medical, Sheffield, UK) treatment with early closure of the defect¹¹ (1 patient) and anastomotic leakage with an abscess for which a defunctioning ileostomy was created (1). [§]Anastomotic leakage for which a defunctioning ileostomy was created (2 patients), small bowel herniation necessitating laparotomy (1), diagnostic laparoscopy because of a prolonged postoperative ileus (1; no mechanical cause was observed) and suspected anastomotic leakage (1). CRD, close rectal dissection; TME, total mesorectal excision. ^{¶¶} χ^2 for trend, except [#]Mann–Whitney *U* test and ^{**}Fisher's exact test.

dissection. After ligation of the superior rectal artery, TME dissection was performed in the areolar avascular plane along the mesorectal fascia down to the pelvic floor. When using the CRD technique, the superior rectal artery was not ligated. The mesorectum was left in place and dissected in the non-anatomical perimuscular plane, thereby preserving the mesorectal fat. The dissection was performed close to the muscular tube of the rectum using an ultrasonic device (UltraCision[®]; Johnson and Johnson Medical, New Brunswick, New Jersey, USA).

Outcomes

The primary outcome was long-term pouch compliance, determined by barostat measurements; these results will be published at a later stage. Secondary outcomes were 30-day or in-hospital morbidity, QoL and pouch function in the first year after surgery. Complications were graded according to the Clavien–Dindo classification of surgical complications⁷. If a patient had multiple complications, only the most severe complication was graded. Anastomotic leakage was considered to be present when diagnosed by CT or during reintervention.

QoL was assessed using the Short Form 36 (SF-36[®]; QualityMetric, Lincoln, Rhode Island, USA) and the GIQLI (Gastrointestinal Quality of Life Index) at baseline

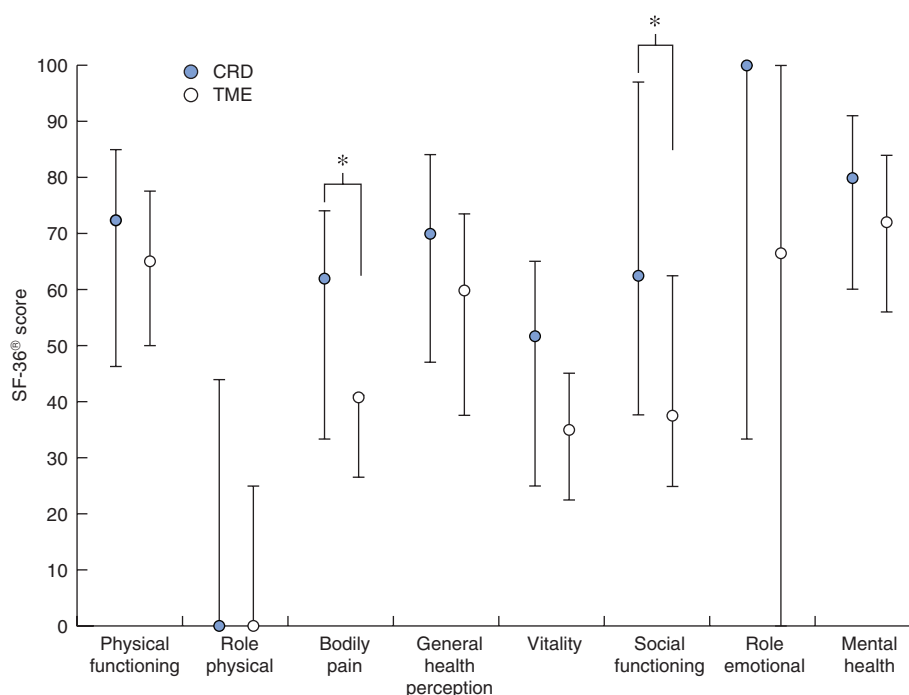


Fig. 2 Median (i.q.r.) Short Form 36 (SF-36[®]; QualityMetric, Lincoln, Rhode Island, USA) scores at 1 month after surgery. A higher score indicates a better quality of life. CRD, close rectal dissection; TME, total mesorectal excision. **P* < 0.050 (Mann–Whitney *U* test)

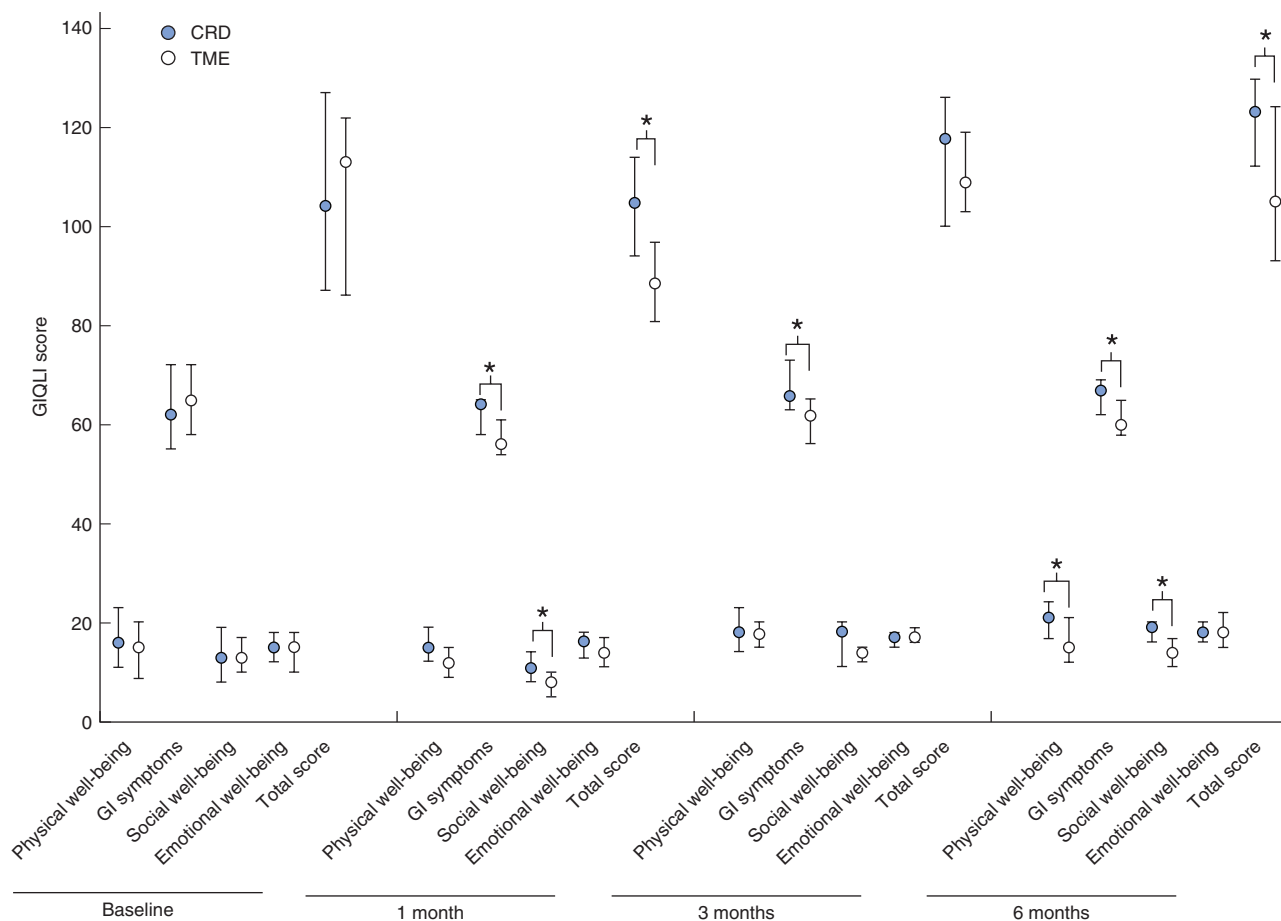


Fig. 3 Median (i.q.r) GIQLI (Gastrointestinal Quality of Life Index) scores at baseline and 1, 3 and 6 months after surgery. A higher score indicates better well-being. CRD, close rectal dissection; TME, total mesorectal excision; GI, gastrointestinal. * $P < 0.050$ (Mann–Whitney U test)

and 1, 3, 6 and 12 months after surgery^{8,9}. Pouch function was assessed using the COREFO (COloREctal Functional Outcome) questionnaire at similar intervals. The COREFO contains five scales: incontinence, social impact, defaecation frequency, stool-related aspects (such as pain during bowel movements, blood loss), and use of medication¹⁰. Missing data were reported and no data imputation was performed. Sexual or urinary dysfunction was not enquired after separately. All baseline and 30-day or in-hospital morbidity data were collected prospectively by the investigators using a case record form.

Statistical analysis

All analyses were carried out according to the intention-to-treat principle. Because of the lack of literature regarding barostat measurement data on CRD for restorative proctocolectomy, a sample size calculation could not be performed. The sample size of 30 patients

in each arm was therefore chosen based on clinical relevance as well as feasibility of performing the study within a particular time frame. Categorical data are presented as frequencies and percentages. Continuous data are presented as mean(s.d.) or median (i.q.r.), according to distribution. To compare dichotomous data, the χ^2 test or Fisher's exact test was used. The independent t test was used to compare mean values, and the Mann–Whitney U test for skewed data. Morbidity graded by the Clavien–Dindo classification⁷ was compared with the χ^2 test for trend. All tests were two-sided and $P < 0.050$ was deemed significant. Statistical analysis was performed using SPSS[®] for Windows[®] version 19.0 (IBM, Armonk, New York, USA).

Results

Sixty patients were assigned randomly to CRD or TME. All patients received the allocated intervention. Rectal

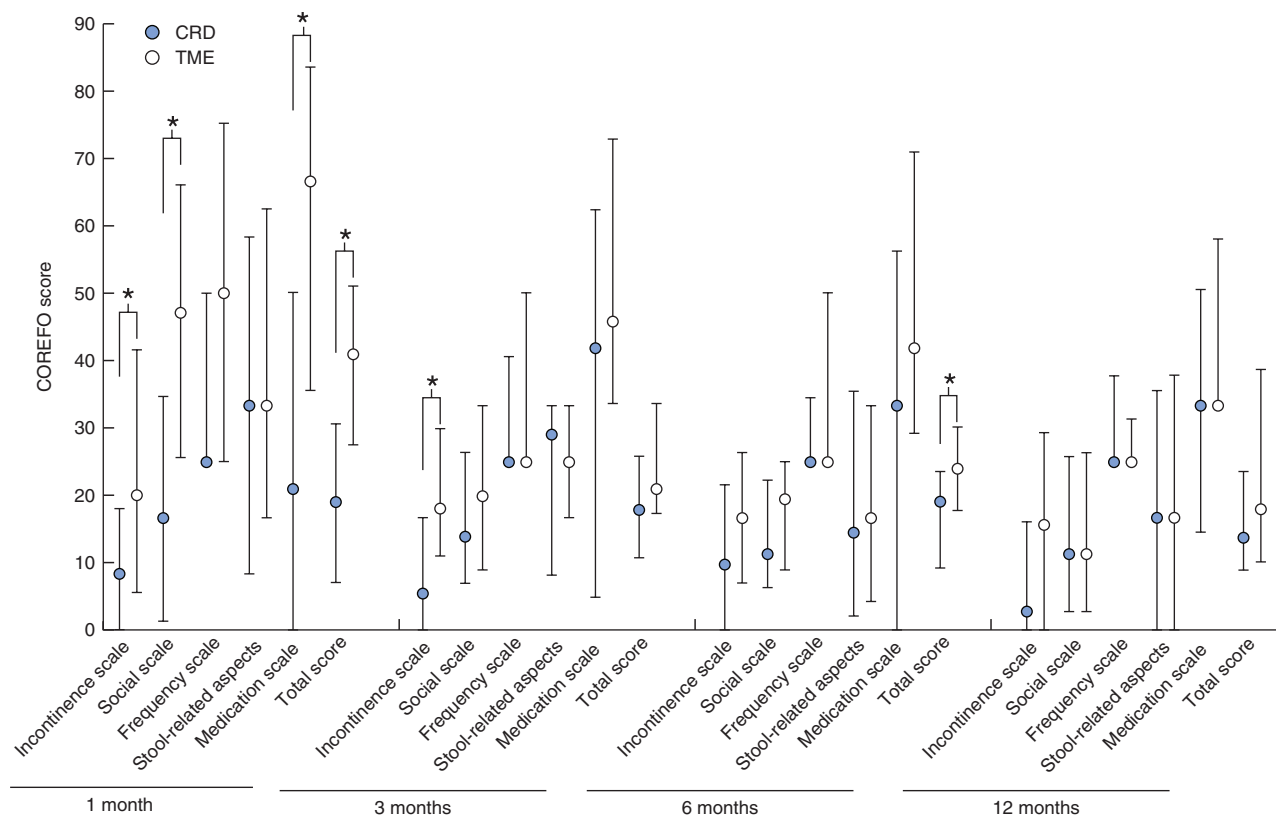


Fig. 4 Median (i.q.r) COREFO (COloREctal Functional Outcome) scores at 1, 3, 6 and 12 months after surgery. A higher score indicates an increased level of continence disturbance. CRD, close rectal dissection; TME, total mesorectal excision. * $P < 0.050$ (Mann–Whitney U test)

carcinoma was detected during surgery in one patient, who was excluded from further analysis. Overall, 28 patients were included in the CRD group and 31 in the TME group (Fig. 1). Baseline characteristics of the patients are shown in Table 1, and Table 2 shows the characteristics of the surgery. Eight patients had a primary defunctioning ileostomy. Decision on ileostomy in the CRD group was related mostly to poor general condition of the patient; indications for ileostomy in the TME group were: severe proctitis (3 patients); prednisone use greater than 20 mg/day (1 patient); extensive additional surgery (abdominal wall reconstruction with biological mesh; 1 patient); handsewn anastomosis (1) and an incomplete doughnut after stapling (1).

Of the 59 procedures, 49 were performed or supervised by surgeon A, eight by surgeon B (who initially trained surgeon A), and two by surgeon C. All CRD procedures were done by surgeon A. Of all procedures (both CRD and TME), 38 (64 per cent) were carried out by a colorectal fellow under supervision of surgeon A or B.

Morbidity and hospital stay

Significantly more severe (grade III) complications were seen in the TME group ($P = 0.027$) (Table 3). The overall 30-day anastomotic leak rate was 7 per cent (2 of 28 patients) in the CRD group and 19 per cent (6 of 31) in the TME group ($P = 0.259$). When comparing consultant surgeons with fellows, no statistical difference was observed in anastomotic leak rate (data not shown). The reasons for creating a secondary defunctioning ileostomy more than 30 days after pouch construction in four patients were late presentation of anastomotic leak or high defaecation frequency. Length of stay did not differ between the groups (Table 3).

Quality of life

At baseline, the SF-36® and GIQLI response rates were 95 and 97 per cent respectively. At 1, 3, 6 and 12 months after surgery, the SF-36®, GIQLI and COREFO response rates were 80, 80 and 75 per cent, 78, 80 and 66 per cent, 80, 82 and 75 per cent, and 78, 80 and 70 per cent respectively.

Response rates for the COREFO were lower because of exclusion of patients with an ileostomy, for whom this questionnaire is not valid. Baseline measurements for the SF-36[®], GIQLI and COREFO showed no differences between the groups for any of the subscales.

At 1 month after surgery there was a significantly higher score on two subscales of the SF-36[®] (bodily pain and social functioning) in the CRD group (Fig. 2). At 3, 6 and 12 months the results were similar in both groups. At 1, 3 and 6 months after surgery, patients in the CRD group scored significantly better on several subscales of the GIQLI (Fig. 3), although results were similar at 12 months (data not shown). The COREFO scores at 1 month after surgery were significantly better in the CRD group for the incontinence scale, social impact scale, medication scale and total score (Fig. 4). At 3 months the CRD group scored significantly better only on the incontinence scale, and at 6 months only on the total score. By 12 months all differences had disappeared.

Discussion

In this study CRD was associated with a lower rate of severe complications than TME in patients undergoing IPAA. In terms of QoL, SF-36[®], GIQLI and COREFO scores showed only short-term differences on several subscales, in favour of the CRD technique, but QoL was similar for the two techniques at 12 months.

A significant difference in the number of severe complications was found, possibly explained by the higher anastomotic leak rate in the TME group. This difference is difficult to explain, as a greater proportion of patients in the CRD group used more than 20 mg steroids per day in the perioperative setting. It has been suggested^{12,13} that prior use of biologicals might be responsible for an increase in anastomotic leakage; however, only one patient in the TME group used antitumour necrosis factor before surgery. Furthermore, the increased rates of primary defunctioning ileostomy and anastomotic leakage in the TME group could not be explained by preferences or the results of individual surgeons or fellows.

Possible explanations for the lower leak rate in the CRD group include the sealing of a small posterior defect and not creating a dead space behind the pouch, preventing formation of a presacral abscess, as also suggested by Rink and co-workers¹⁴. By preserving the posterior mesorectum, complications related to a presacral cavity may be reduced. Abscess formation behind the pouch may result in anastomotic disruption. It could be argued that the omentum can be used to fill the cavity, but, although that is

true, omentum often does not fill the space immediately behind the anastomosis at the level of the pelvic floor. When there is leakage, pus and debris push the omentum upwards, creating a presacral collection in any case. Proponents of the CRD technique argue that sexual and bladder function are better preserved. A hypothetical argument against preservation of the mesorectum is that the newly constructed pouch needs space to dilate. It can also be speculated that, by preserving the mesorectum and its nerves, proprioception might be different as opposed to removing the mesorectum, possibly resulting in a greater awareness of pouch-filling.

It is the authors' policy not to perform a routine ileostomy, appreciating the added morbidity of the loop ileostomy and its closure. Leaks are treated aggressively with Endo-SPONGE[®] (B. Braun Medical, Sheffield, UK) therapy, enabling quick closure of the presacral space; this may avoid the adverse outcome of chronic sepsis on pouch function¹¹.

Operating time differed between the two groups. However, when considered as single- or multiple-stage procedures, the difference was no longer significant. CRD is challenging because of the limited exposure as a result of the preserved mesorectal fat, particularly when done via a Pfannenstiel incision.

Better QoL was observed in the CRD group on several subscales of the SF-36[®], GIQLI and COREFO at 1, 3 and 6 months after surgery, possibly because of the greater number of severe complications in the TME group. The consistent differences for the gastrointestinal symptoms scale of the GIQLI and the incontinence scale of the COREFO suggest that patients in the TME group had problems mainly with functioning of the pouch. It is hard to find an explanation for this notable difference between the TME and CRD groups.

To date, this is the only study that has randomized patients having an IPAA between CRD and TME. Even though the primary outcomes are still awaited, the significant difference in morbidity is clinically relevant. The major limitation of this study is the difference in baseline characteristics, which occurred despite randomization. However, a study with a small sample size is more susceptible to baseline differences, owing to a larger chance of sampling error¹⁵. A better design might have been to perform randomization stratified for primary restorative proctocolectomy or completion proctectomy. In addition, it would have been helpful to determine the Ulcerative Colitis Disease Activity Index score at the time of surgery; unfortunately, it is not possible to determine a disease index objectively in retrospect. Surgeon A was the operating or supervising surgeon for the majority of patients

in this study, and this might have influenced the external validation of the results. However, both techniques, CRD and TME, will be performed in tertiary inflammatory bowel disease referral centres by a limited number of experienced surgeons.

Patients having a two-stage procedure would be expected to have fewer complications. However, in the TME group, with the highest complication rate, 24 of the 31 patients had a completion proctectomy. Furthermore, a larger proportion of patients in the CRD group had polyposis. These patients are generally less likely to develop postoperative complications because their preoperative condition is generally better than that of patients with inflammatory bowel disease. However, the small number of patients with polyposis in this study would not be likely to influence the results.

Advocates of the CRD technique, as first described by Lee and Dowling¹⁶ in 1972, claim better preservation of sexual function in men. In a retrospective study, Lindsey *et al.*⁴ found a similar rate of impotence in men having close rectal or mesorectal dissection for inflammatory bowel disease. It would have been interesting to study sexual dysfunction in this series as well.

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