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ORIGINAL ARTICLE

A sustaining rod increases necrosis of loop ileostomies: a randomized controlled trial

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Abstract
Purpose Defunctioning loop ileostomies (LI) are commonly used in colorectal surgery to reduce the potentially detrimental consequences of anastomotic leakages. However, stoma-related morbidity is high with up to 75% of patients having local complications. The aim of this study was to investigate the effect of a sustaining rod on the local complication rate.
Methods In this prospective, multi-center, randomized controlled trial, subjects were allocated to either a rod or a rod-less protocol (NCT00959738). The primary outcome was local morbidity as measured by a stoma specific morbidity score (SSMS) during the first 3 months postoperatively.
Results Between August 2008 and July 2014, a total of 122 patients were enrolled in the study, of which 78 (63.8%) completed the study [44 (56.4%) rod, 34 (43.6%) rod-less]. There was no significant difference in the SSMS between the two groups. The incidence of necrosis or partial necrosis, however, was significantly increased in the rod group: 13 (29.5%) vs. 1 (2.9%) in the rod-less group ($p < 0.01$). The retraction rate did not differ significantly between the groups: two (4.5%) in the rod vs. five (14.7%) in the rod-less group ($p = 0.13$). High body mass index (BMI > 26) was associated with an odds ratio of 5 ($p < 0.01$) for severe stoma complications.
Conclusions A rod-less technique for loop ileostomies reduces the risk of stomal necrosis, with a high BMI being an independent risk factor for stomal complications.

Keywords Loop ileostomy · Local stomal complications · Defunctioning stoma · Sustaining rod

Introduction

Anastomotic leakage rates following colorectal anastomoses range from 4 to 26% [1, 2]. Leakage is known to be correlated with worse prognosis after curative resection [3–5]. In addition, anastomotic leakage has been associated with a 6–22% mortality rate [6] and a 10–100% risk of being left with a permanent stoma [6, 7]. Defunctioning loop ostomies are commonly used in surgical practice to protect distal colorectal anastomoses. A defunctioning stoma reduces the rate of clinically relevant anastomotic leakages and is thus recommended in surgery for low rectal cancer [1, 8, 9]. Loop ileostomies (LI) are associated with fewer postoperative complications and a better quality of life compared to loop colostomies [10–14].

Stomal retraction is a specific complication of LI [15]. Traditionally, the insertion of a bridge ("rod") to support both limbs was advocated to prevent this problem. Many techniques and materials have been described (e.g., Jackson-Pratt drain, plastic rod, local skin flap, fascial bridges, subcutaneous sutures) [16–21]. Nevertheless, due to the supporting rod, difficulties may occur when applying a stoma bag and leakage of feces onto the skin may occur, even with correct eversion of the afferent limb [16, 19, 22]. Moreover, a supporting rod may allow for stoma formation with some degree of mesenteric tension. The resulting ischemia is

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thought to contribute to the morbidity in LI. Common complications of LI with a bridge include skin irritation in up to 54% [23–25], stomal retraction in 8–22% [15, 24], and erosion of skin in 5% [25, 26]. This has led to the proposal of rod-less techniques [19]. In a randomized trial with 57 patients allocated to either a "bridge" or "bridge-less" protocol, no significant difference in stoma retraction rate and stoma activity between the two groups was found [27].

In a previous pilot study, we retrospectively analyzed 30 patients having an ileostomy with a rod and 30 patients with rod-less ileostomies [28]. Morbidity was determined according to a scoring system ranging from 0 to 4 points for any given set of possible complications (edema, bleeding, necrosis, skin irritation, abscess, stenosis, retraction, fistula, prolapse, parastomal hernia, incomplete diversion). Significantly more patients were found to have severe postoperative complications (>5 points) in the rod group (36.7 vs. 13.3%, $p = 0.04$). The number of patients managing to achieve complete self-care of their stoma was significantly higher in the rod-less group (80.0 vs. 56.7%, $p = 0.05$).

In this prospective, randomized controlled trial, we aimed to test the hypothesis that a rod-less defunctioning loop ileostomy is associated with fewer postoperative complications.

Method

Design

A prospective, multi-center, randomized controlled, two-armed trial was conducted. Between August 2008 and July 2014, all patients presenting for an operation potentially requiring LI were asked to participate. Exclusion criteria were age <18 years, patients with long-term use of corticosteroids (>15 mg prednisolone equivalent daily), or patients on sirolimus. Four surgical institutions took part in the study. Site A was a university hospital; sites B–D were large regional (cantonal) hospitals in Switzerland. For Swiss Standards, these are all medium to high volume colorectal centers.

The study was performed adhering to the CONSORT guidelines [29]. Ethical clearance was granted from the regional ethics committee, and the protocol was registered in an international registry (clinical trial number NCT00959738). All participants had given written consent before inclusion. The patients underwent randomization to a *rod* and *rod-less* protocol before surgery. The randomization was performed by the study coordinator with the use of computerized random numbers. After a definitive decision to perform an LI was made, patients' study identification number and treatment allocation, as determined by the randomization list, were requested by phone.

Interventions (operative procedures)

Participating surgeons at the different study sites received an instruction video to ensure a standardized surgical technique for LI formation. The LI site was selected and marked by a stoma specialist nurse or the surgeon preoperatively. A 2-cm skin disc with adjacent subcutaneous tissue was excised, followed by a cross incision into the anterior rectus sheath. After blunt separation of the rectus muscle, the posterior layer of the rectus sheath and the peritoneum were also incised in a cruciate fashion. The incision of the abdominal wall was dilated to admit two fingers. The terminal loop of the ileum was exteriorized with the help of a rubber tube (commercial surgical rubber tubing, 1/8″ outer diameter) inserted through a small mesenteric incision close to the bowel. The afferent limb was placed cranially to the efferent limb in order to prevent rotation of the mesentery. No fixation stitches to the abdominal fascia were performed. After closure of the laparotomy, the rubber tube was replaced by a plastic rod (Stomocur®; For Life Inc., Berlin, Germany) or removed according to the randomization. Half of the circumference of the antimesenteric bowel wall was incised, followed by four U-stitches using 4/0 PDS (polydioxanone, synthetic, absorbable monofilament) at both limbs. The two bowel limbs were everted thereafter by tying the previously put PDS stitches. Babcock clamps or small Langenbeck retractors were used to support the eversion of the bowel. A minimal eversion of the afferent limp of 2–2.5 cm was required. The formation of the ileostomy was then completed with additional PDS stitches. The rod was left in place until removal of the stitches, which was done at the discretion of the stoma nurse.

Outcome measurements

The primary endpoint was the stoma specific morbidity score, already used in the pilot study [28]. In brief, morbidity was graded according to a scoring system ranging from 0 to a maximum of 4 points. Parameters were edema, bleeding, necrosis, skin irritation, abscess, stenosis, retraction, fistula, prolapse, parastomal hernia, and incomplete diversion. The score is described in detail in Table 1.

Secondary endpoints were (1) time until the patient was able to empty the stoma bag, fix a new bag and, change the stoma plate by him-/herself; (2) time used by the stoma nurses for instructing and assisting patients (measured in total hours, from the intervention up to 3 months postoperatively); (3) quality of life, assessed with a Stoma Quality of Life Scale (SQOLS) questionnaire [30] before surgery as well as 2 weeks and 3 months postoperatively; and (4) predictive factors for stomal complications: age, body mass index (BMI), length of intestinal mesentery, and intraabdominal infection.

Table 1 Stoma Specific Morbidity Score (SSMS)

Parameter	Description	Points
Edema	Without consequences	1
	Impairment of stoma nursing	2
Bleeding	Compression alone sufficient	1
	Bed side stitching sufficient	2
	Hematoma	3
	Surgical revision	4
Necrosis	Border only	1
	Centrally superficial	3
	Complete	4
Skin irritation	Partial erythema	1
	Circumferential erythema	2
	Exsudation	3
	Ulceration	4
Dehiscense of suture/ abscess formation	<¼ of circumference	2
	Between ¼ and ½ of circumference	3
	>½ of circumference	4
Stenosis/obstruction	Conservative treatment	3
	Surgical revision necessary	4
Retraction	Between 1 cm and skin level	2
	Skin level	3
	Below skin level	4
Fistula	Conservative treatment	3
	Surgical revision necessary	4
Prolapse	No impairment	2
	Impairment	3
	Surgical revision necessary	4
Parastomal hernia	No impairment	2
	Impairment	3
	Surgical revision necessary	4
Incomplete diversion	No complication	2
	Surgical revision not necessary	3
	Surgical revision necessary	4
Total		42

Length of intestinal mesentery was measured with a ruler. The ileal loop was mobilized in front of the relaxed abdominal wall. Then distance was measured between the skin and transition of mesentery to intestine was determined.

Tertiary endpoints included (1) *length of hospital stay*, measured in days after intervention; and (2) changes in eversion (measured in mm) of the stoma nipple at postoperative days 2, 4, 6, 8, 14, 30, 60, and 90.

Statistics

Power analysis was performed with the retrospective data analysis of 60 patients (30 patients per group) [28]. A sample size of 180 (90 per group) was calculated to achieve an 80% power to detect a difference of 20% in the primary outcome (local morbidity during the first 3 months postoperatively) with a significance level (alpha) of 0.05 (two-sided Fisher's exact test).

Continuous variables were compared with unpaired *t* test when normally distributed. Wilcoxon rank-sum test was applied for non-normally distributed continuous variables. Binary outcomes were compared using chi-squared tests. Predictive factors for stomal complications were evaluated with multivariate Poisson regression.

All statistical analyses were computed using STATA® Intercooled version 14 (Stata Corporation, Texas, USA). *P* values were two-sided, and $p = 0.05$ was considered the threshold for statistical significance. Data are presented as mean ± standard deviation if normally distributed, or as median (interquartile range).

Results

Patients' demographics

A total of 122 were recruited for the study between August 2008 and July 2014. Sixty-one were allocated to the *rod* and 61 to the *rod-less* protocol. The overall drop-out rate was 44 (36%). Twenty-seven (22%) patients received either no stoma or a colostomy (intraoperative decision not to perform a LI), and 14 (11%) patients were lost to follow-up. One patient was randomized two times and was allocated into both study arms by mistake, with no further data collected from this patient. One patient was excluded from the analysis due to high-dose steroid treatment (>15 mg per day). Of the 78 patients remaining for analysis, 44 were in the *rod* and 34 in the *rod-less* arm. The mean follow-up was 165 (95% CI 121–209) days. Based on the number of predicted patients, initial study duration was set at approximately 3 years. The study was prolonged due to a much lower patient accrual rate. After another 3 years, the study was terminated according to protocol. The randomization and follow-up process is illustrated by a CONSORT flow chart in Fig. 1.

Table 2 summarizes the demographical data of the study population. There were no significant differences between the two groups in terms of gender, age, malignancies, BMI, nicotine consumption, and laparoscopic/open surgery. There were also no differences found with regard to manual dexterity and cognitive capacity, as measured with a timed test of money counting [31]. The main indication for the formation of an ileostomy was a low anterior resection.

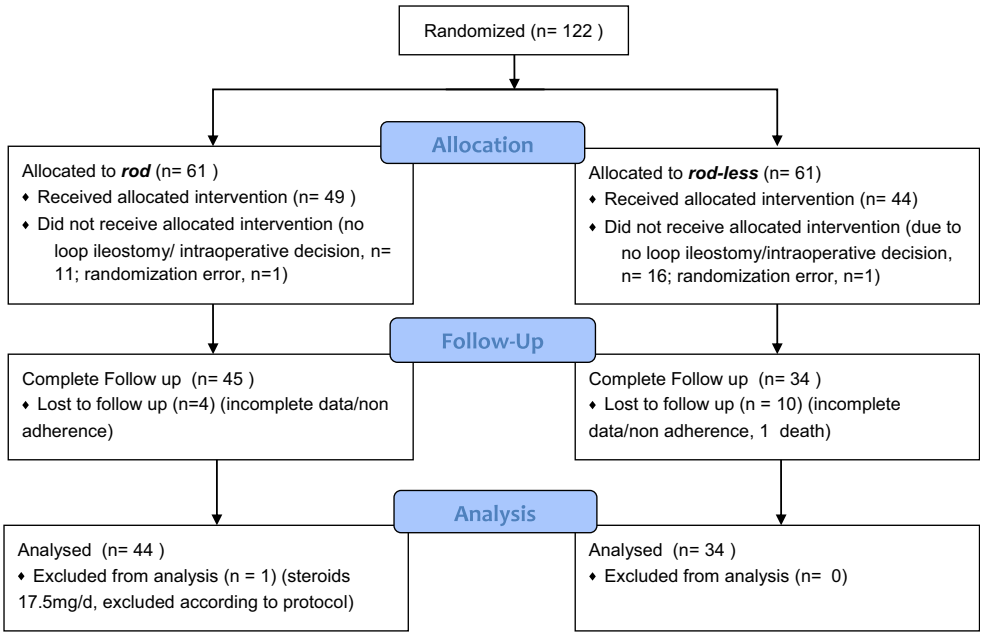

Fig. 1 CONSORT flow chart showing the patient flow according to CONSORT Statement

The majority of patients (71%) were included into the study by center A, followed by 17% of patients in center B. Centers C and D included 10 and 2%, respectively.

Table 2 Demographics and surgical indications

	Rod	Rod-less
Total number (*n*)	44	34
Age: mean (SD)	64.3 (10.5)	59.3 (12.3)
Gender: % male	78	64
BMI: mean (SD)	26.1 (4.3)	26.2 (4.2)
Diabetes: *n* (%)	6 (13.7)	3 (8.8)
Nicotine consumption: *n* (%)	3 (6.8)	2 (5.9)
Chronic dialysis: *n* (%)	0 (0)	0 (0)
Use of psychopharmaceuticals: *n* (%)	6 (14)	4 (12)
ASA classification[a] (25 missing): *n*		
I	3	5
II	11	18
III	11	4
IV	0	1
Operation time: min (SD)	326.9 (99.8)	303.1 (113.4)
Laparoscopy: *n* (%)	23 (52.3)	21 (61.8)
Conversion rate: *n* (%)	5 (11.4)	8 (23.5)
Indication for the formation of LI		
Anterior resection	36	28
Reversal of Hartman's situation	2	2
Ileoanal pouch formation	2	2
Diversion for various reasons (perianal fistula, fistula after pouch formation, pelvic sepsis)	4	2

[a] *ASA classification* American Society of Anesthesiologists classification, *SD* standard deviation

Primary endpoints

The detailed results are depicted in Table 3. The incidence of necrosis (including superficial necrosis)—greater than 0 points for parameter 3 in SSMS—was significantly increased in the *rod* group when compared with the *rod-less* group (Fig. 2). While more severe necroses (>2 points for parameter 3 in SSMS) were observed in the rod group (3/44, 6.8%), this trend was not significant ($p = 0.12$). The overall incidence of more severe necrosis was 3.8%. There was no difference in the overall stoma specific morbidity score between the rod and the rod-less protocol. However, the frequency distribution of the stoma specific morbidity score revealed lower frequencies in the rod-less group for a SSMS <6 (Fig. 3). Also, no differences were found among the remaining parameters of the stoma specific morbidity score (bleeding, skin irritation, abscess, stenosis, fistula, prolapse, parastomal hernia, incomplete diversion) and in the retraction rate (Fig. 2) between the two treatment arms.

Secondary endpoints

The detailed results are depicted in Table 3. There was no significant difference in the time until the emptying of the stoma bag was carried out by the patient him-/herself and average time until self-sufficiently fixing a new stoma bag or changing a stoma plate.

The overall time used by the stoma nurses for instructing and assisting patients within the first 3 months postoperatively did not differ between groups.

High body mass index (BMI) was significantly correlated with an increased stoma complication score. The

Table 3 Primary and secondary outcomes

	Rod	Rod-less	*p* Value
SSMS, mean ± SD	3.2 ± 2.3	2.8 ± 2.0	n.s.
SSMS, median (IR)	3 (2–4)	2.5 (1–4)	n.s.
Necrosis (partial and complete)	13 (29.5%)	1 (2.9%)	0.002
Retraction	2 (4.5%)	5 (14.7%)	n.s.
Time until self-sufficiently empty bag, days, median (IR)	7 (5–9)	7 (4.5–9.5)	n.s.
Time until self-sufficiently change bag, days, median (IR)	10 (8–14)	10 (7–12)	n.s.
Time until self-sufficiently change plate, days, median (IR)	12.5 (10–15)	10 (7–15)	n.s.
Time used by stoma nurse, min, median (IR)	297 (240–405)	335 (240–420)	n.s.

SSMS stoma specific morbidity score, *IR* interquartile range, *SD* standard deviation, *n.s.* not significant

median BMI of the population was 26 kg/m^2. With a high BMI (BMI > median), the odds ratio was increased fivefold to have a high SSMS in the univariate analysis. The odds ratio was 5 for a SSMS >3 ($p < 0.01$) and 4.8 for an SSMS >4 ($p = 0.025$). This correlation remained significant ($p = 0.02$) when adjusting for age, diabetes, operation time, and randomization in a multivariate model ($n = 65$). No correlation was found between age, length of intestinal mesenterium, diabetes, nicotine consumption, duration of operation, ASA classification, and the occurrence of stomal retraction, necrosis, or overall stoma complications.

The changes of Stoma Specific Quality of life over the study period are shown in Fig. 4. No differences were found between the treatment groups at any time point of the study. Within the first 2 weeks after the operation, overall SQOLS score decreased by 17.3 (13.2–21.4) points from the baseline ($p < 0.01$). SQOLS remained significantly decreased by 14.3 (9.9–18.7) points after 3 months when compared with the baseline, $p < 0.01$ (Fig. 4). Patient satisfaction, measured by SQOLS, of those suffering from a retraction and/or necrosis was significantly decreased by 8.3% ($p = 0.03$) compared to patients without retraction and/or necrosis.

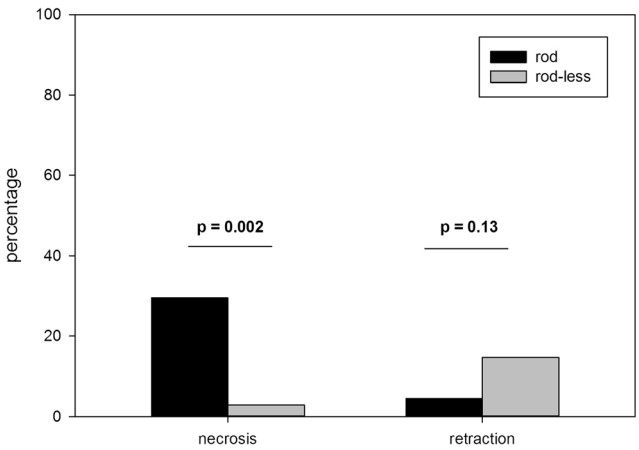

Fig. 2 Percentage of necrosis and retraction in the rod and rod-less group

Tertiary endpoints

The mean hospital stay was 18.8 ± 19.5 days in the *rod* and 14.1 ± 11.2 days in the *rod-less* group ($p = 0.09$).

The eversion of the stoma decreased continuously until the end of the follow-up after 74 (65) days. The mean (95% confidence interval) change in millimeters was 3.3 (1.1–5.6) in the afferent and 3.0 (1.3–4.7) in the efferent limb. For the afferent limb, changes in eversion for rod versus rod-less group were 2.6 mm (8.8) vs. 4.2 mm (10.0), $p = 0.48$. For the efferent limb, these were 2.5 mm (6.6) and 3.5 mm (7.9), respectively.

Discussion and conclusions

The aim of this study was to evaluate the morbidity of adding a rod in the formation of a loop ileostomy as compared to a rod-less technique. A significantly increased risk of partial necrosis was found when using a sustaining rod, while retraction rates were higher in the rod-less group, although not significantly.

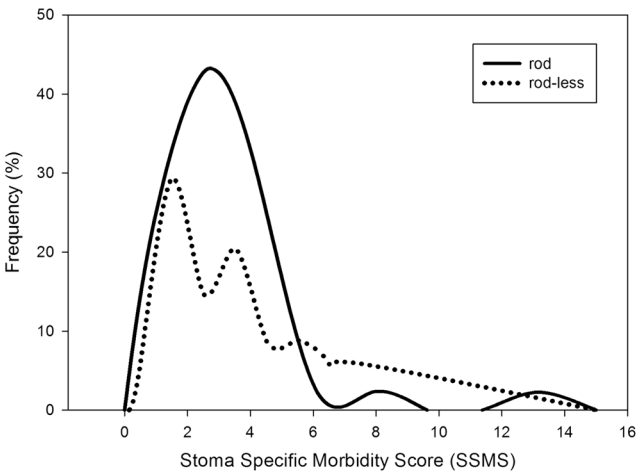

Fig. 3 Frequency distribution of stoma specific morbidity score. The frequency distribution of stoma specific morbidity score (SSMS) is shown separately for the two treatment arms

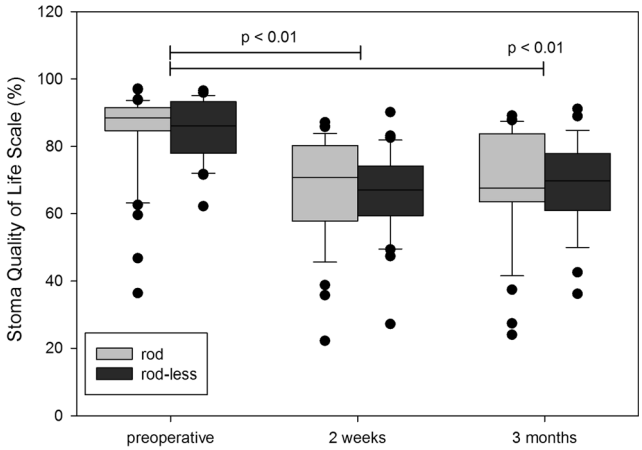

Fig. 4 Stoma Quality of Life Scale pre- and post-surgery. The extent of the *box* indicates interquartile range (25th and 75th percentiles); the midline of the *box* corresponds with the 50th percentile (median). *Whiskers* indicate the 10th and 90th percentiles. All outliers are shown

While a 29.5% incidence of stomal necrosis in the rod group (versus 2.9% in the rod-less group) may seem rather high, this includes all degrees of necrosis, ranging from minimal necrotic changes up to complete stomal necrosis. When looking at the rate of complete necrosis alone, our results compare well with the previous literature reporting rates around 5% [25, 26].

An increased rate of necrosis might be explained by direct arrosion of the tissue by the rod, with an increased tension of the mesentery and a consecutively decreased tissue perfusion possibly contributing to this effect. Microcapillary flow probes would be necessary to better understand the local changes in perfusion.

We were unable to show any differences in the stoma specific morbidity score (SSMS) between the two groups, as was expected from the initial pilot study. This might be explained by the fact that while morbidity from retraction was found more often in the group without a sustaining rod, necrosis was predominantly found in the group with a sustaining rod. The incidence of retraction (5.7%) compares well with others [15, 27]. No differences were found between the two groups with regard to the secondary endpoints serving as surrogate parameters for clinical outcome, such as hospital stay, self-sufficiency in stoma care, instruction time required by the stoma specialists, and overall quality of life (QoL). However, patients suffering from retraction and/or necrosis demonstrated a significantly decreased quality of life. Furthermore, we found a significant 17.3% decrease ($p < 0.01$) in QoL within the first 2 weeks post-surgery, as compared to the preoperative score. This decrease in the Stoma Quality of Life Scale (SQoLS) [30, 32, 33] remained consistent until 3 months post-surgery.

With regard to the identification of possible risk factors for the occurrence of stoma complications, only a high BMI could be identified as an independent risk factor. With a high BMI, the odds of having a high SSMS was increased fivefold. The thicker subcutaneous layers and the often shortened, fatty mesentery may lead to the formation of a stoma under tension, resulting in a reduced blood supply to the stoma and subsequent retraction or necrosis.

This is one of the largest randomized trials comparing the formation of a LI with or without a rod and the first randomized trial providing evidence that the use of a supporting rod results in certain aspects of morbidity, such as stoma necrosis, being increased. The major limitation of this study was the inclusion of less than half of the patients (43.3%) needed to detect a 20% difference in the primary endpoint. This was due to the much lower accrual rates than initially estimated. This in turn was mainly due to two reasons. First, centers C and D stopped including by July 12, 2011, and November 23, 2009, respectively, due to changes in responsible personnel. Second, the need of LI formation was frequently abandoned due to an intraoperative change in strategy. This may reflect an overall trend in colorectal surgery toward reducing the rate of defunctioning LI formation.

A recent report of a large prospective cohort study, comparing rod and rod-less procedures, included 515 patients and is therefore statistically better powered than the current study [34]. However, by being an observational study, this design is more prone to bias. The findings of both studies are well in line, since both studies were unable to confirm previously observed increased rates of retraction when refraining from a sustaining rod. On the other hand, using a rod was significantly associated with the risk of local complication, in the current study especially stomal necrosis. Routine application of a rod cannot be recommended for loop ileostomy formation.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflicts of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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