

Original Research Article

A method of ileostomy closure associated with a low anastomotic leak rate: does operative time matter?

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ABSTRACT

Background: Anastomotic leaks (AL) are serious post-operative complications associated with a high morbidity following routine ileostomy closure. Studies comparing standard methods of closure show no difference in outcome. The benefit of longer operative time has not been investigated.

Methods: Baseline characteristics and surgery outcomes for all patients who had an ileostomy closure from 1994-2015 at a single centre by a single surgeon were extracted from medical records. An electronic literature search of EMBASE, PubMed was performed to identify systematic reviews of Randomised controlled trials (RCT) reporting pooled leak rates and operative time for stapled vs hand sutured anastomosis. A meta-analysis using data from 4 eligible RCT was used to compare outcomes between the new versus standard techniques.

Results: A total of 415 patients underwent ileostomy closure during the study period with no leaks (0%, 95%CI 0-0.9); compared with 10 leaks reported in 649 patients (1.5%, 95%CI 7-28) from four trials. This risk difference of 1.55% corresponds to a Number needed to treat (NNT) of 66. Two individual trials reported leak rates of 2-3% which were statistically significantly different to the case series leak rate ($p < 0.05$). Mean operative time was 170 minutes (95%CI 163-177) ($p < 0.05$) using the modified functional end-end anastomosis and stapled: 67 minutes (95%CI 59-74) and hand-sutured: 80 minutes (95%CI 70-90).

Conclusions: The increased operative time performing our modified stapled functional end-end anastomosis is associated with a very low leak rate compared with stapled or hand-sutured anastomosis.

Keywords: Anastomotic leak, Leak, Ileostomy closure, Operative time, Ileostomy reversal

INTRODUCTION

Closure of ileostomy is a common and routine procedure performed in many colorectal units in the management of colorectal cancer, inflammatory bowel disease and diverticulitis.¹⁻³ Considering the increasing prevalence of these conditions in the western world, it is expected that more of these operations will be performed on a regular basis. Closure of an ileostomy normally follows construction of a loop ileostomy which functions as a diverting stoma; protecting a newly formed distal (lower) anastomosis from the complications of Anastomotic leakage (AL).^{4,5} Loop ileostomies do not in and of

themselves remove the risk of anastomotic leakage in distal anastomoses; however they have been shown to minimise the morbidity of this serious condition.^{3,6,7} In the literature, the risk of anastomotic leaks is decreased from 28% to 10% in the presence of a diverting ileostomy.⁵

The reversal of an ileostomy itself is a relatively simple procedure, yet it is associated with a high morbidity reaching 67% and a mortality up to 6%.^{8,9} As with distal anastomoses, closure of an ileostomy is itself associated with anastomotic leakage which ranges from 0-10% and is responsible for increased hospital stay, re-operation in 10.4% of patients and death.⁸⁻¹⁴

METHODS

This is a retrospective case series of all patients who underwent closure of ileostomy by a single surgeon at a major tertiary hospital between February 1994 to July 2015. Eligible patients were identified using both public and private medical, operative and pathology records. The technique for ileostomy closure was uniform across all patients.

Baseline characteristics including: age, gender, surgical indication, primary pathology were collected and analysed (Table 1). Anastomotic leak, the interval between ileostomy construction and reversal (time to closure) and operative time were collected from the hospital operation report.

Exclusion criteria

Patients with missing operative time and incomplete data were excluded from the study.

Primary end points

AL was based on clinical (tachycardia, fever, hypotension, abdominal pain) and radiological (anastomotic fluid collection) findings; and operative time was defined as the start to the completion of surgery.

Secondary end points

Mortality was defined as post-operative death of any cause up to 30 days from the time of surgery as recorded in the medical record.

Surgical technique

All patients had a water-soluble contrast enema to assess the integrity and patency of the anastomosis prior to ileostomy closure. All patients underwent routine pre-operative work-up. Under a general anaesthetic, an elliptical incision was made around the muco-cutaneous junction and the ileostomy with surrounding adhesions were carefully dissected from the rectus sheath and peritoneal cavity. Small enterotomies were formed on the antimesenteric border of each limb. A single fork of the GIA™ 100 mm linear cutting stapler was inserted in each limb. After approximating both limbs, a single firing of the linear stapler formed a single enterotomy. Babcock clamps were used to grasp and retract opposite borders of the anterior and posterior enterotomy lines. A second firing of the reloaded stapler at 90 degrees to the previous staple line completed the stapled anastomosis. Four sutures of 4/0 PDS were then placed. The first was placed at the longitudinal (first) staple line to add mechanical strength to the anastomosis. Two sutures were placed to invert each end of the transverse (second) staple line. Finally, one inverting suture was placed at the point of intersection of the two staple lines. The abdominal wall was closed using interrupted non absorbable nylon sutures and the skin was

closed with loose interrupted 2/0 prolene sutures in a subcuticular fashion.

Historical comparison

The anastomotic leak rate and mean operative time using the study modified technique was compared with standard techniques using data from published trials in systematic reviews of stapled and hand sewn techniques. Eligible RCTs were identified from systematic reviews comparing the two techniques and reporting anastomotic leak rates and operative times. A meta-analysis was performed to estimate the anastomotic leak rates and operative times for stapled and hand sewn techniques and compare with outcomes for our modified technique.

Literature search

A literature search was performed using PubMed and EMBASE to identify eligible systematic reviews of RCTs. We used a combination of the search terms with the Boolean operators and or- 'ileostomy closure', 'anastomotic leak', 'stapl*', 'sudur*', 'operative time', 'loop ileostomy', 'ileostomy reversal', 'closure', 'ileostomy'.

Study selection

We restricted our selection to systematic reviews of randomised control trials comparing operative time and anastomotic leak rates in stapled and hand sewn ileostomy closures. Non randomised studies were excluded due to the potential of bias. Other inclusion factors required the trials to report: primary diagnosis, pathological site and duration of interval between ileostomy construction and closure. Systematic reviews with duplicate trials and missing data were excluded.

After applying our criteria, six potential systematic reviews were identified.¹⁴⁻¹⁹ With the exception of one review all included the same trials.¹⁴ Four were excluded for missing data and duplication. We selected the systematic reviews: Gong et al for data on anastomotic leakage and Loffler et al for operative times.^{16,17}

Statistical analysis

Case series data were analysed using IBM SPSS 22.0. Meta-analysis to compare primary outcomes from our case series and pooled results from published trials was performed using Stata 12.0 (StataCorp, College Station, TX, USA). Categorical variables were expressed as event rates in percentages (%) with 95% confidence interval (95%CI). Fisher's exact test was used to compare event rates between individual studies. Continuous variables were summarised as mean and Standard deviation (SD), and a 95%CI was calculated for mean operative time. A student t test was used to compare operative time between individual studies. Statistical heterogeneity was assessed using χ^2 ($p < 0.05$) and the extent of heterogeneity was

determined using I^2 . This was interpreted as <30 % (low) and >80% (high). For statistical significance, we considered non overlapping confidence intervals and $p < 0.05$ to be significant.

RESULTS

A total of 670 patients underwent closure of ileostomy using the modified stapled functional end to end anastomosis during the study period, 235 were excluded due to missing operative time. Baseline characteristics of the case series are presented in (Table 1). Of the 415 remaining patients, there were 217 (53%) males and 198 (47%) females. Mean age was 65. The commonest surgical indication was rectal cancer (59%) followed by diverticular disease (11.2%). Anterior resection with diverting ileostomy (95%) was the main primary operation performed. Mean time to closure of ileostomy was 15 weeks and average hospital stay was 5 days. There were 144 (35%) patients who had a concomitant para-stoma hernia repair.

Historical comparison

A total of 649 patients from four RCT were included (Table 2).²⁰⁻²³ These trials were conducted in four different countries (USA, UK, Germany and Russia) from 1993-2010. Patients were evenly balanced in both stapled (N=330) and hand sewn (N=319) groups. Patient demographics were even across all trials (Table 3) with more males (60%) undergoing ileostomy closure. Rectal cancer was the commonest surgical indication and anterior resection followed by pelvic pouch formation was the most

frequent primary surgery. Mean time to closure varied from 3-6 months. Risk of bias assessment was performed on all of the included trials. Random sequence generation and allocation concealment were unclear in two of the four trials.^{20,21} Computer generated random numbers and central randomizations were used in the two other trials.^{22,23} Blinding of outcome assessment was unclear in all four trials. Attrition bias was reported in two studies.^{16,20} There were no withdrawals or patients lost to follow up in the Hull trial, whereas Loffler et al reported their findings on an Intention to treat basis (ITT).

Anastomotic leaks

Of the 415 patients in the case, there were no leaks during the study period (0/415) (0%, 95%CI 0-0.9) (Table 4). However, the likelihood of an anastomotic leak using the modified stapled technique was <9 per 1000 based on confidence intervals (Figure 1). Pooled results from the four RCT reported 10 leaks (N=649) (1.55%, 95%CI 0.7-2.8) this interprets to a leak rate of 7-28 per 1000. There was low statistical heterogeneity between studies ($I^2=31%$). Two individual trials reported leaks between 2-3%.^{21,23} One trial- Loffler et al reported leaks in both stapled (3%, 95%CI 1-7.3) and hand suture (1.85%, 95%CI 0.4-5.4).²³ The Hasegawa trial reported a 2.9% leak rate in their hand sutured group (2.9%, CI 95% 0.3-10.3).²¹ The difference between each of these trials and our series was statistically significant ($p < 0.05$). When the results of all four trials were pooled, the difference was not statistically significant. If all 670 patients are included, the results become statistically significant.

Table 1: Baseline patient characteristics.

Parameters	Values
Age (mean)	65.0
Gender	Male 217 (52.7%)
	Female 198 (47.3%)
Primary diagnosis	Rectal carcinoma 238 (59.2%)
	Diverticular disease 45 (11.2%)
	Recto sigmoid carcinoma 25 (6.2%)
	Sigmoid carcinoma 27 (6.7%)
	Crohn's disease 9 (2.2%)
	Ulcerative colitis 6 (1.5 %)
	Vesico-colic fistula 6 (1.5%)
	Endometriosis 11 (2.7%)
	Other 48 (11.5%)
Primary surgery	Anterior resection 396 (95.5%)
	Ileo-anal pouch (J pouch) 12 (3%)
	Ileo-rectal anastomosis (IRA) 6 (1.4%)
	Right hemicolectomy 1 (0.25%)
Time to closure	15.1 weeks
Mean operative time	170.71 mins
Para-stoma hernia	144 (35%)
Surgical technique	Modified functional end-end anastomosis
Parameters	Values

Note: Other: rectal perforation, pelvic abscess, rectal adenoma, dysplastic polyp, Familial adenomatous polyposis (FAP).

Table 2: Characteristics of included trials.

Study	Country	Study type	Surgical methods	Surgical experience	Primary end point
Hull et al, 1996	USA	RCT	STA vs HS	Staff+residents	Hospital stay
Hasegawa et al, 2000	UK	RCT	STA vs HS	Consultants+registrars	Event rate
Shelygin et al, 2010	Russia	RCT	STA vs HS	Consultants+registrars	Operating time
Loffler et al, 2012	Germany	RCT	STA vs HS	Consultants	Bowel obstruction

Table 3: Baseline patient characteristics of all studies in the meta-analysis including case series.

Study (year)	Surgical method (N)	Gender M/F (%)	Age (mean)	Surgical indication	Time to closure (weeks)
Karam et al (2022)	Modified functional (415)	217/197 (53/47)	65	Rectal cancer IBD diverticulitis	3.8
Hull et al (1996)	STA (31)	16/15 (52/48)	43	Crohn's disease	3.5
	HS (30)	17/13 (56/44)	37		
Hasegawa et al (2000)	STA (71)	33/38 (46/54)	46	All requiring loop ileostomy	5.5
	HS (70)	37/33 (53/47)	42		
Shelygin et al (2010)	STA (63)	33/30 (52/48)	58	Rectal cancer	2.5
	HS (56)	29/27 (52/48)	56		
Loffler et al (2012)	STA (165)	105/58 (68/32)	65	Rectal cancer	6
		113/52 (64/36)	65		

Table 4: Anastomotic leaks according to study and technique.

Study	Method	Leaks (%)	CI 95%	P value	
Karam et al (2022)	Modified stapled	0/415 (0)	0-0.9	0.029	
Hull et al (1996)	Stapled	0/31 (0)	0-12		
	Hand sewn	0/30 (0)	0-12.2		
Hasegawa et al (2000)	Stapled	0/71 (0)	0-5.2		
	Hand sewn	2/70 (2.9)	0.3-10.3		
Shelygin et al (2010)	Stapled	0/63 (0)	0-5.9		
	Hand sewn	0/56 (0)	0-6.6		
Loffler et al (2012)	Stapled	5/165 (3.1)	1-7.3		0.002
	Hand sewn	3/163 (1.85)	0.4-5.4		0.023
Pooled et al	Stapled	5/330 (1.5)	0.5-3.5		
	Hand sewn	5/319 (1.55)	0.5-3.6		
	Combined	10/649 (1.55)	0.7-2.8		

Table 5: Anastomotic leaks according to study and technique.

Study	Method	Mean operative time (minutes)	SD (minutes)	CI 95%
Karam 2022	Modified stapled	170.71	68	163-177
Hull 1996	Stapled	60	16.3	54-66
	Hand sewn	74.7	21.5	67-83
Hasegawa 2000	Stapled	38	92.6	16-60
	Hand sewn	42	100.3	18-66
Shelygin 2010	Stapled	71.5	7	70-73
	Hand sewn	87.3	11	84-90
Loffler 2012	Stapled	76.5	29.3	71-81
	Hand sewn	91.5	43.7	85-98
Pooled	Stapled	67	39	59-74
	Hand sewn	80	40	70-90

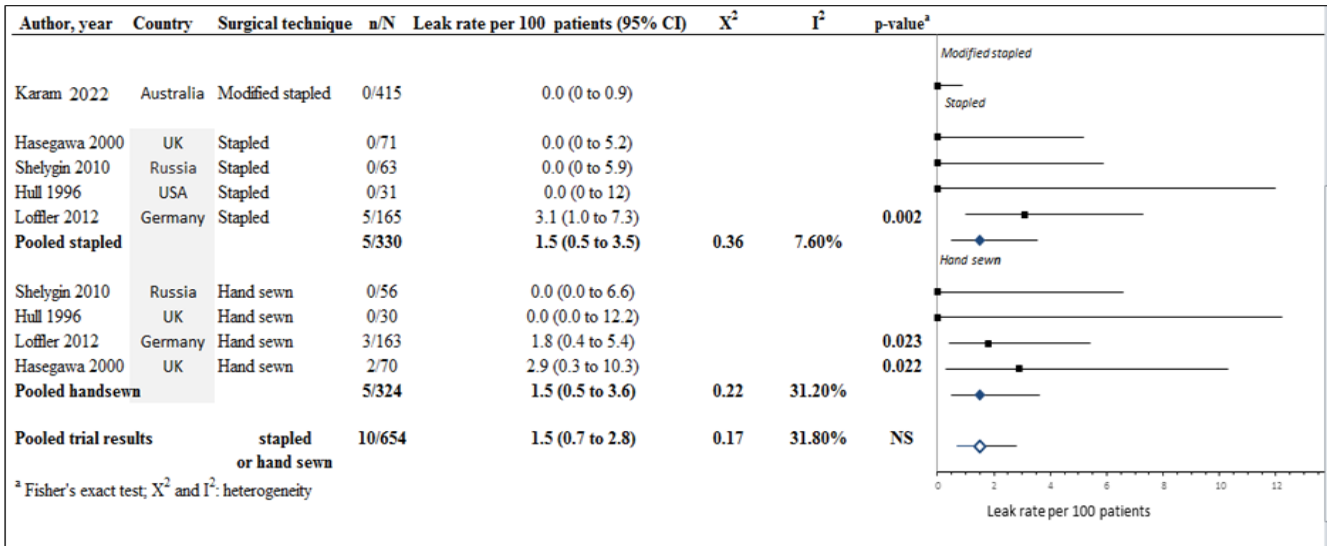


Figure 1: Leak rate per 100 patients and 95%CI according to surgical technique.

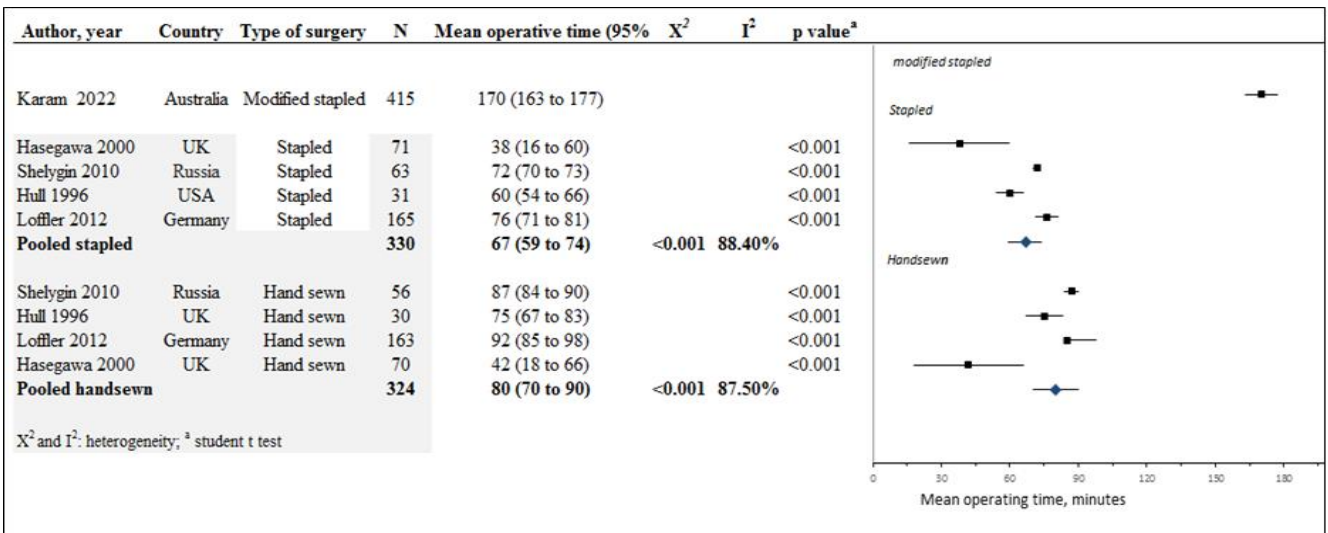


Figure 2: Mean operative time and 95%CI.

Operative time

All four trials reported mean operative time and standard deviation (SD) (Table 5). Statistical heterogeneity was high (I² 88%) between each trial and the case series. Mean operative time in our series was 170 minutes (95%CI 163-177). This was significantly longer than mean operative time in each of the four trials and reached statistical significance (p<0.05) (Figure 2). The difference in operation time between the modified stapled and stapled techniques ranges from 132 minutes to 94 minutes (median=66 minutes) and from 128 minutes to 78 minutes, (median=81 minutes) in the hand sewn technique. The modified stapled operative time was also significantly longer than the pooled trial operative times for stapled: 67 minutes (95%CI 59-74) and hand sewn: 80 minutes (95%CI 70-90).

Mortality

There were no deaths in our study or the historical trial group.

DISCUSSION

This is the first study which investigates the benefits of longer operative time using a modified technique for ileostomy closure and low anastomotic leak rates. The findings from this large case series indicate our modified functional end to end anastomosis technique is safe, with no anastomotic leaks or deaths reported in 415 patients, consistent with a leak rate of fewer than 9 per 1000 (95%CI 0- 0.9%). Our results compare favourably with the reported leak rates in high quality RCTs of standard techniques. We also report the benefits of long operative time required to perform this technique with a mean time

of 170 minutes, which is at least twice as long as the mean operative times of standard techniques from published RCTs included in our meta-analysis.

Anastomotic leakage following ileostomy closure is a serious complication with significant morbidity.⁷ Currently, no safe and acceptable leak rate has been found in the literature and this is likely a reflection of the variation in event rates according to the quality of published studies.¹⁵ Two of the largest retrospective studies have shown reduced leak rates using stapled devices.^{7,24} Over the last few decades, stapled anastomoses have become popular due to reduced post-operative Small bowel obstruction (SBO) and shorter operative time.^{2,22} Furthermore, their practical utility and shorter operative time have not been shown to minimize anastomotic leakage in randomised control trials.^{21,2} The relationship between anastomotic leaks and operative time has not been investigated in ileostomy closure. We investigated the safety of a modified stapled technique with a longer operative time that has not been complicated by anastomotic leaks or deaths.

Based on our meta-analysis of trials, the anastomotic leak rate of standard hand sewn and stapled techniques is estimated at 1.55%, suggesting our technique may provide a small clinically important 1-1.55% absolute risk reduction for reducing leak rates, however we were not able to conclude a statistically significant difference.

This is possibly explained by the fact that our series (N=415) was underpowered to demonstrate a 1% difference in event rates, however if all 670 patients are included in the series, the difference becomes statistically significant. Hence, we propose a larger cohort is needed to estimate the true effect size of our study. Two of the smaller trials did not report a leak in both stapled and hand sewn groups, however the size of these studies may underestimate the true leak rate as reported in larger trials.²³ A trend favouring our method was seen when compared to the trials that showed a leak ($p < 0.05$).^{21,23} The trial pooled rate of 1.55% is the lowest reported figure from systematic reviews and equates to a number needed to treat (NNT) of 66 when compared to the results of the modified technique.¹⁶ When retrospective studies are included, this is likely to increase above 1.9%.¹⁷ Our choice to limit the meta-analysis to RCTs was to compare our outcomes with the highest quality evidence and most realistic figure in the literature. Whilst the comparative value of our series with pooled results is indirect and limited by possible confounding factors such as surgical skill, the overall benefit of our technique offers a 1.55% risk difference in anastomotic leak reduction and a number needed to treat (NNT) of 66; the best evidence of any published study.

When evaluating trials included in the meta-analysis, the level of clinical and statistical heterogeneity were acceptable; this was evident in patient demographics which were evenly balanced: males slightly dominated all studies and pathologies in the rectum were most common;

a possible reflection of an underlying gender propensity for colorectal disease which is in keeping with the literature.²⁴ We found notable differences in surgical experience when comparing the level of expertise in our case series and the included trials. Ileostomy closures in Loffler et al were all performed by consultants whereas a combination of consultants and trainees were noted in the other trials.²³ This seems to reflect the state of teaching hospitals where the trials were conducted.

There were various documented risk factors for anastomotic leakage present in our series, the strongest of which were male gender and obesity, however post-operative outcome was no different to those without these risk factors.²⁵ None of the trials included in this paper assessed the relationship of risk factors to reported leaks; however, studies assessing pre-operative risk factors have shown a higher likelihood of leakage in such patients.²⁵

The relationship between underlying disease and anastomotic leakage has been previously studied.²⁶⁻²⁸ It has been suggested that anastomotic leakage is more likely to occur in benign conditions such as diverticular disease and inflammatory bowel disease than in colorectal cancer.^{26,28} A possible explanation could be because benign conditions tend to be associated with an inflammatory state that interferes with anastomotic healing.²⁸ There were no notable differences in our series between cancer and non-cancer patients, nor were there differences based on primary surgery. Nevertheless, since the number of patients with benign diseases was small in comparison to cancer patients, negligible differences may not be easily recognisable.

Operative time was considerably longer in our series compared with trials of standard techniques with statistical heterogeneity between studies. When results of each technique were pooled, we found that operative time using our technique was double the hand sewn and almost triple the stapled techniques. This may be explained by a combination of patient factors (obesity) surgical (adhesions from previous surgery) and most importantly, the meticulous nature of the technique. Simultaneous repair of para-stomal hernias occurred in 35% of patients at the time of ileostomy closure which also increased the overall operative time. Concurrent para-stomal hernia repairs reduce the development of post-operative hernias which have been reported to be as high as 9.3 % and eliminate the need for a second operation.²⁹ These patients were not excluded from the study in an attempt to minimize selection bias and improve statistical power. As a result, the true operative time would be expected to be shorter than what we have reported.

A crucial finding of our study is that longer operative time does not increase the likelihood of anastomotic leakage as has been shown previously.^{26,27} This justifies our underlying hypothesis that the extra time spent carefully performing an ileostomy closure may potentially offset the serious complications and costs of anastomotic leaks

associated with shorter operative time. A cost effectiveness analysis would be required to justify the economic benefit for every avoided leak and associated morbidity. Further studies would also be required to investigate the relationship of operative time with other post-operative complications such as wound infections and sepsis.

In the literature, the association between longer operative time and anastomotic leakage is based on studies which report higher post-operative complications in patients undergoing difficult colorectal surgery however this has not been established in ileostomy closure which is a less invasive procedure compared with open laparotomy.²⁶ The underlying premise is that longer surgery increases tissue trauma, blood loss and bacterial exposure.³⁰ Nevertheless the majority of these cases are attributable to complex patients impacting difficult surgery rather than operative time itself.²⁷

At present there is a paucity of evidence which suggest favourable outcomes in longer colorectal surgeries. This is likely influenced by the higher costs associated with longer time in theatre, theatre scheduling as well as the perceived unfavourable functional outcome for these patients. To the best of our knowledge, this is the first and largest study to describe the relationship of longer operative time with anastomotic leakage using a modified form of the functional stapled end to anastomosis, we hope to ultimately challenge current thought by altering attitudes towards increased operative time. In the literature one other study has reported a functional and economic advantage of stapled anastomoses, however there was no significant leak reduction with shorter operative time.²¹ This has also been reproduced in another study.³¹

With regards to secondary outcomes, there were no deaths during the study period. Two of the studies included in the meta-analysis did not report this outcome; the remaining two had no deaths. The mortality rate in our study and historical controls are lower than figures found in the literature.^{9,32} The lack of anastomotic leaks may be a reason for this observation.

We believe our study has important clinical and research implications. Our results raise the hypothesis that the safety of ileostomy closure may be increased by favouring a more meticulous approach eliminating or at least reducing the risk of anastomotic leakage given that evidence for surgical techniques remains inconclusive.¹⁵ This is particularly relevant for the management of patients with known risk factors and pathologies associated with a higher leak potential. A proposed model we offer is that surgeons should recognise these high-risk patients and ensure optimum intraoperative care through careful dissection, avoidance of bowel trauma and enhancing anastomotic blood supply. Whilst patient factors are at times beyond the surgeon's control, a careful surgical approach may well compensate for these factors.

Our findings are promising as they also fit in with evidence on colonic surveillance for colorectal cancer where it has been shown that the additional time taken to perform routine colonoscopies improves the rate of polyp detection and removal whilst ultimately improving patient outcome.³³⁻³⁵ By adding on to existing literature, our results offer a new perspective in the ongoing dilemmas of ileostomy closure. We suggest that a reasonable solution for minimizing anastomotic leakage can be achieved via a more careful and meticulous surgical approach, a finding that has not been previously documented in other trials.

There are obvious limitations in our study to be noted. First, this was a retrospective case series and thus we were limited to examining study endpoints that could be extracted from medical records. Limited access to data also restricted our ability to increase the size of the study and assess other intra-operative variables such as ASA scores. Second, it was not possible to control for confounding factors such as surgical skill and post-operative management that may have biased our estimate of the leak rate associated with the study technique. Third, the sample size of our case series and the pooled trial historical comparison group was underpowered to test for a small clinically important difference in leak rate between our study technique versus standard techniques. It is hoped that the methodological quality of the included trials may compensate for this apparent weakness. Fourth, we were limited to making indirect comparisons with published data, thus advising caution when interpreting these results to avoid the risk of overstatement. Fifth, because of the single centre nature of our study, results may not be generalizable to other centres. Sixth, inter-study differences in end point definitions for anastomotic leak and operative time were a possible source of error which may influence the differences in leak rates and operative time. Despite these inherent limitations of our study, we believe our findings are valuable for hypothesis generation and motivating further research in this field.

CONCLUSION

In summary, the current case series demonstrates a possible benefit of longer operative time using our modified functional end to end stapled anastomosis which is associated with a very low leak rate compared to trial-reported rates for standard stapled and hand sewn anastomoses. A large multicentre RCT is required to quantify the true effect size of this modified technique for reducing anastomotic leakage in closure of ileostomy.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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