Anastomotic leak rates between powered and non-powered circular staplers in left-sided colorectal resection; a retrospective cohort study

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ABSTRACT

AIM: Anastomotic leak (AL) is associated with major post-operative morbidity and mortality. The circular stapler, widely utilised in colorectal anastomosis, has seen a technological change from manual firing stapler (MFS) to powered automated firing stapler (PAFS). PAFS may reduce user error and technique variation and may be associated with reduced AL rate. The primary aim of the study was to assess differences in AL rate between MFS and PAFS. Secondary aims were to assess differences in length of stay (LOS) and 30-day mortality.

METHODS: This was a retrospective, single surgeon review of patients undergoing resection with anastomosis using a circular stapler between 2016 and 2023. A historical MFS group (n=105) and a study PAFS group (n=112) were identified. Demographics, comorbidity, operation type, neoadjuvant therapy, AL, LOS and 30-day mortality were recorded.

RESULTS: The populations were comparable, with no significant difference in demographics, BMI, ASA grade, neoadjuvant radiotherapy use or type of operation. The PAFS group contained more non-malignant cases, 35% vs 18% (p=0.01). AL rate was 11.4% in the MFS group and 3.6% in the PAFS group (p=0.04). Fifty-eight percent of the anastomotic leaks in the MFS group needed surgery, compared to zero from the PAFS group (p=0.09). Mean LOS was 10 days in the MFS group and 6 days in the PAFS group (p = 0.01). Thirty-day mortality was 0.9% from the MFS group and zero from the PAFS group (p=0.48).

CONCLUSION: While acknowledging confounders may have affected outcomes, in this study PAFS was safe and associated with a significant reduction in AL and LOS.

Anastomotic leak (AL) is a feared complication among colorectal surgeons that remains common despite improved understanding of technical and patient-related factors. Frequency of AL varies by centre and type of bowel resection. Large international studies have reported a frequency of AL for left-sided resections between 8% and 15%.[1,2,3] Specifically in Aotearoa New Zealand, a review of anterior resections at a provincial hospital found an AL rate of 10.5%.[4] Furthermore, the effects of colorectal AL are devastating both in terms of patient outcomes and financial implications for the healthcare system. AL is associated with a five-fold increase in 30-day mortality and a two-fold increase in local malignancy recurrence at 5 years.[5] With regard to financial impact, AL in America have been shown to cost over US$30,000 per index admission more than cases without AL.[6] While in Europe the cost is even more stark at €54,000 additional cost per case with AL.[7] Given the sequelae of AL, performing a colorectal anastomosis is a critical step and all efforts should be made to minimise the rates of AL in colorectal surgery.

Traditionally colorectal anastomoses were hand-sewn; however, by the late 1970s, the end-to-end anastomosis (EEA) circular stapler for left-sided colorectal anastomosis formation came into use. After several iterations, the late 2010s saw the introduction of the powered automated firing stapler (PAFS). Proposed benefits of powered firing compared to a manual firing stapler (MFS) include reduced force required to fire the stapler, improved stapler head stability and equal compression of tissues throughout the anastomosis.[8] Contemporary studies suggest a reduction in AL rates when using the PAFS for left-sided colorectal anastomosis.[9,10] However, the PAFS has been associated with a higher rate of staple-line bleeding.[11]

We hypothesise that use of the PAFS for left-sided

colorectal anastomosis will lead to a reduction in AL rate and therefore better patient outcomes when compared to manual firing stapler (MFS) use. The primary aim of our study is to compare AL between MFS and PAFS. Secondary aims of the study are to assess 30-day mortality, re-operation rate and length of hospital stay (LOS).

Methods

This was a single centre retrospective cohort study of consecutive cases performed at a regional hospital in Aotearoa New Zealand from June 2016 to October 2023. All left-sided resections, i.e., left hemi-colectomy, sigmoidectomy and high, low and ultra-low anterior resections, performed by a single colorectal surgeon, prospectively recorded on a personal database, were included in the study. The surgeon had been a consultant colorectal surgeon for 4.5 years and had performed approximately 360 colorectal resections by the start of the data collection period. During this period patients were managed according to well-established surgical checklist and Enhanced Recovery After Surgery (ERAS) protocol.[12] The surgeon switched to preferential utilisation of 29mm PAFS (ETHICON ECHELON CIRCULAR™) from 28mm MFS (COVIDIEN EEA™) in June 2020.

Operation notes of all eligible patients were reviewed retrospectively, and patients who underwent an anastomosis with an EEA circular stapler met inclusion criteria for the study population. Patients were excluded if the anastomosis was hand-sewn or if there was uncertainty regarding which stapler was utilised. All patients had routine intraoperative "bubble-test" of the newly formed join.

The primary outcome, AL, was defined either radiologically, as documented on post-operative imaging report, or as documented in operative notes if taken back to theatre. Patients were investigated for AL only if clinically indicated.

Data were collected from online medical records by two authors. Outcomes included AL, post-operative complications defined by Clavien-Dindo (CD) score three or above, LOS and mortality at 30 days. Demographic data included age, gender, ethnicity, pre-operative ASA grade and BMI. Disease and surgical factors included underlying pathology (malignant vs benign), neoadjuvant treatment, height of anastomosis (high, low, ultra-low) and formation of covering ileostomy were also recorded.

Data for the two cohorts were analysed using R Studio 3.6.1, with statistical significance of differences for categorical data assessed using Fisher's exact test, and statistical significance of differences for continuous data assessed using the Two-Sample *t*-Test. A p-value of less than 0.05 was deemed to be statistically significant.

Results

A total of 222 patients had left-sided anastomosis between October 2016 and October 2023. Anastomoses formed between October 2016 and May 2020 used the MFS, and anastomoses formed between June 2020 and October 2023 used the PAFS. Between October 2016 and May 2020 there were 106 left-sided bowel resections. One case was excluded as they had end stoma formation rather than an anastomosis.

A total of 116 left-sided colorectal resections were performed between June 2020 to October 2023. Four cases were excluded; two because they had stoma formed rather than anastomoses, two more because they had hand-sewn anastomoses (see Figure 1).

After exclusion, there were 105 patients who had anastomosis performed by MFS and 112 by PAFS for analysis.

Both cohorts showed marked homogeneity with regard to demographics and pre-operative comorbidity (see Table 1). There was no significant difference regarding type of operation, inclusion of covering ileostomy or use of neoadjuvant radiotherapy between each group (Table 2). There was a significantly higher rate of resections for malignancy in the MFS group, 82% (n=84), than the PAFS group, 65% (n=70, p=0.01).

The MFS group had an AL rate of 11.4% (n=12) compared to 3.6% in PAFS (n=4), which was statistically significant (p=0.04). The risk difference was 7.8%, giving a number needed to treat of 13, suggesting that for every 13 anastomoses performed with PAFS rather MFS, one leak would be prevented.

The mean LOS for the MFS group was 10.3 (SD=8.6) days, while for the PAFS group it was 5.9 (SD=4.9) days (p=0.01). Excluding patients who had AL, patients who had an anastomosis formed with the MFS had a mean LOS of 9.7 days, whereas the PAFS group had a mean LOS of 7.6 days (p=0.01).

For patients found to have AL, both MFS (n=12) and PAFS (n=4) patients had a mean LOS of 15 days (p=0.5). There was no significant difference among the leak cohort between the rate of

Figure 1: Study recruitment & exclusion flow chart.

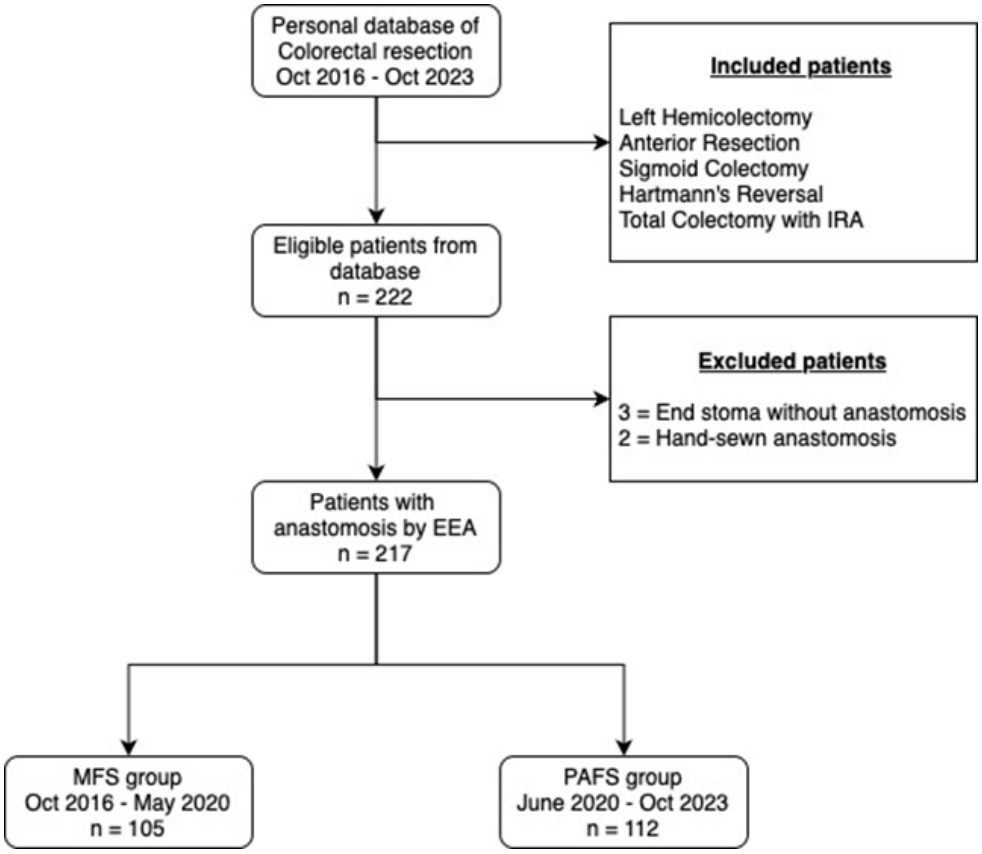

Table 1: Demographic and comorbidity characteristics of each cohort.

	Manual firing stapler (n=105)	**Powered firing stapler (n=112)**	**P-value**
Mean age (years)	65 (SD=14.4)	64 (SD=13)	0.9
Sex			
Male	55% (n=58)	54% (n=61)	0.99
Female	45% (n=47)	46% (n=51)	
Ethnicity			
NZ European/Pākehā	82% (n=86)	81% (n=91)	0.96
Māori	10% (n=10)	11% (n=12)	0.82
Other European	8% (n=8)	5% (n=6)	0.59
Other/Not recorded	<1% (n=1)	3% (n=3)	0.62

Table 1 (continued): Demographic and comorbidity characteristics of each cohort.

Mean BMI (kg/m2)	27 (SD=5.3)	28 (SD=8.1)	0.15
Mean ASA	2 (SD=0.6)	1.9 (SD=0.5)	0.25

Table 2: Operation type, ileostomy formation rate and neoadjuvant radiotherapy rate. *ULAR = Ultra-low anterior resection, LAR = Low anterior resection, HAR = High anterior resection.

	Manual firing stapler (n=105)	**Powered firing stapler (n=112)**	**P-value**
Elective operation	96% (n=101)	97% (n=109)	0.71
Laparoscopic	69% (n=72)	64% (n=72)	0.56
ULAR*	31% (n=33)	26% (n=29)	0.37
LAR*	14% (n=15)	15% (n=17)	0.85
HAR*	33% (n=35)	40% (n=45)	0.33
Other	22% (n=23)	19% (n=21)	0.61
Covering ileostomy	40% (n=42)	36% (n=32 out of 88 complete data)	0.09
Neoadjuvant radiotherapy	18% (n=19)	18% (n=20)	1

pre-operative radiotherapy, covering ileostomy nor malignant pathology.

Fifty-eight percent of the AL occurring with the MFS (n=7) required a return to theatre, whereas none of the AL occurring with the PAFS needed operative management (p=0.09). One patient died at 30 days in the MFS group, whereas none of the PAFS group died at 30 days (p=0.48).

Of the 151 patients that had resections for malignancy, 82 were in the MFS group and 69 were in the PAFS group. Nine (11%) of the patients in the MFS group who had resection for malignancy developed AL, whereas three (4%) of the patients in the PAFS developed AL. However, this difference was not statistically significant (p=0.23)

The cost of the MFS was NZ$850 per unit, compared to the PAFS at NZ$1,067. The cost of a surgical bed at our hospital was NZ$1,150 per night. Comparing the costs of each stapler use based on average LOS, PAFS cost NZ$4,383 less per use than MFS.

Discussion

This study found a significant reduction in the incidence of left-sided colorectal AL with the PAFS, with results comparable to recent international studies.[6,7,11] While we did not look specifically at the reasons why the PAFS may have lower AL rates, this is likely to be multifactorial. We posit that consistency in the firing mechanism of the PAFS, and the reduced force needed to be applied to fire the stapler, are important factors in forming reliable anastomoses. However, the change of stapler from MFS to PAFS involved a change in manufacturer and therefore further differences in stapler technology may also have influenced outcomes.

Current literature suggests that malignant resections have a higher risk of AL than anastomoses formed after resection of non-malignant pathology.[13] Our results showed a trend towards reduced rate of AL for anastomoses formed with PAFS during malignant resections, however the results did not reach statistical significance.

PAFS use was associated with a significantly shorter average LOS, even when accounting for AL. Furthermore, none of the patients who had an AL with the PAFS required a return to theatre. That said, reduced LOS and reduced return to theatre may also reflect factors such as evolution in clinical practice and experience gained over time.

As the data pertained to a single surgeon's experience, the technical skills for each operation are consistent. However, there may be a learning effect seen with outcomes improving over time. The firing of each stapler is usually performed by the assistant, rather than the primary operator. The study did not record who fired the stapler on each occasion, making it impossible to comment on the experience or learning curve of each stapler user.

Our results associate the introduction of PAFS with a financial saving, with a basic cost analysis showing a saving of over NZ$4,000 with each use of the PAFS. This excludes additional costs such as further interventions or critical care required to manage AL, but it does not account for inflation over time. There is a green cost implicated with powered stapler use, however, that may be offset by reduced AL rate, subsequent interventions and LOS, and it is not explored in this study.

As a small, retrospective study, accuracy was dependent on medical records; this was a limitation of our study. To further the evidence base in this field it would be interesting to do a multicentre, multi-operator study.

In conclusion, we found a reduced rate of AL and a reduced LOS when switching from MFS to PAFS for left-sided colorectal anastomoses. This adds to the body of evidence that the PAFS appears to be safe and may lead to improved patient outcomes. As the body of data regarding the use of this stapler grow it will be interesting to see what further conclusions may be drawn.

COMPETING INTERESTS
The authors declare that they have no financial or material interests that relate to the research described in this paper. There are no conflicts of interest to declare.

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