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Intestinal Anastomosis During Enterostomy Takedown Using a 5 mm Miniature Endostapler Compared to Conventional Handsewn Technique☆

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ABSTRACT

Aim: Enterostomy takedown is common in neonates with Hirschsprung's disease, anorectal malformations, or necrotizing enterocolitis. Stapled bowel anastomosis has become routine in adults, but size of up to 12 mm diameter precludes performing enterostomy takedown in young infants using regular intestinal staplers. After the introduction of miniature (5 mm diameter) staplers, we increasingly used them for enterostomy takedown. This study compares enterostomy takedown using the miniature stapler (MS) to the conventional hand-sewn (HS) technique.

Methods: Retrospective review of all children <3 years of age undergoing enterostomy closure at our institution from 2008 to 2023 were retrospectively reviewed. Demographics, operative times, complications, and outcomes were compared between those who underwent the procedure using MS versus HS technique. Data are quoted as median (range).

Results: A total of 102 patients were enrolled, including MS ($n = 26$) and HS ($n = 76$) anastomoses. There were no statistical differences in age, sex, or indication for enterostomy. Enterostomy takedown using MS was faster [82.5 (44–218) versus 147 (52–381) minutes, $p < 0.001$) and associated with earlier commencement of feedings [2 (1–6) versus 4 (1–24) days, $p = 0.001$], as well as shorter length-of-stay [6 (2–20) versus 17 (3–52) days, $p < 0.001$), compared to the HS technique.

Conclusions: This is the first study that systematically evaluates the novel 5 mm ministapler for enterostomy takedown in young children. Its use was associated with quicker operative times, earlier feeding and shorter hospital stay. These findings are especially relevant in children with co-morbidities who do not tolerate longer anesthesia times. Randomized, controlled trials should be performed to prospectively confirm these findings.

Level of Evidence: Level III, retrospective comparative study.

1. Introduction

Before miniature (5 mm) stapler devices were available, stapled enterostomy closure was only applicable for older children and adults because of a size discrepancy between the stapler and the bowel lumen. However, most pediatric colorectal surgeries are performed in neonates for indications such as necrotizing enterocolitis (NEC), anorectal malformations, Hirschsprung disease, or intestinal atresia. Consequently, there is very little research on stapled intestinal anastomosis in infants and young children.

The use of adult-size endostaplers for intestinal anastomosis has been shown to be safe and effective for intestinal lumen size over 10 mm [1], with shorter operative times and similar complication rates [2]. However, they have not gained widespread acceptance in pediatric colorectal surgery.

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Around a decade ago, 5 mm endostaplers were introduced commercially and have been used for a variety of pediatric operations, including thoracoscopic pulmonary lobectomy [3], division of the fistula in anorectal malformations [4], and duodenal atresia repair [5]. The 5 mm stapler has been evaluated for intestinal anastomosis in adult New Zealand White rabbits, in which it demonstrated acceptable performance [6]. A case series of five pediatric patients who underwent an open surgical intestinal anastomosis using the 5 mm stapler showed good outcome without long-term follow-up [7].

In our department, the 5 mm endostapler was introduced in 2015. Since then, we have used the device in a variety of operations including appendectomy, lobectomy, duodenal atresia repair, varicocele ligation, serial transverse enteroplasty (STEP), and others. We have also increasingly employed the 5 mm stapler for enterostomy closure in infants and young children, particularly in those with relevant co-morbidities who may not tolerate longer anesthesia times.

In this study, we retrospectively compared enterostomy closure using the novel 5 mm endostapler to the traditional hand-sewn anastomosis in terms of operative times, complications, and outcomes.

2. Materials and methods

All children less than 3 years of age undergoing enterostomy closure at our institute from 2008 until 2020 were included retrospectively in the study. The patients were divided into two groups; those who had their enterostomy reversed by a side-to-side stapled anastomosis using a 5 mm endoscopic stapling device (JustRight 5 mm Stapler, Bolder Surgical, Louisville, USA), and those who underwent enterostomy takedown via end-to-end conventional hand-sewn technique, as well as tapering of the bowel caliber by antimesenteric incision, if needed. In the stapler group, the distal opening for insertion of the stapler was either closed by another stapler fire using a second magazine, or sutured closed using a running 4-0 polyglactin suture.

Technique employed for enterostomy closure was based on date of presentation (all patients who presented before 2015 underwent hand-sewn anastomosis), as well as surgeon's preference. Therefore, some patients who presented after 2015 also underwent handsewn anastomosis.

Exclusion criteria included age older than >3 years (chronologic age), anticoagulation, and severe cardiac or other co-morbidities expected to impact on operative time.

The patients' data were analyzed regarding operative time, intraoperative and postoperative complications, time to first feeds (as a measure of postoperative ileus), and hospital stay. Statistical analysis was performed using the Mann-Whitney-U test, or chi-square analysis, as appropriate. Operative time, postoperative length of hospital stay, and time to oral feeding was calculated by two-sided Mann-Whitney-U test for unpaired variables using *astatsa* statistical software (https://astatsa.com/WilcoxonTest/). A p-value of <0.05 was considered statistically significant. Numeric values were expressed as median (range).

The study was evaluated by the local ethics board and deemed exempt from formal analysis due to the retrospective and anonymous analysis. Written informed consent for the procedure was obtained from all families.

3. Results

3.1. Demographics

Over the course of the study interval, a total of 91 patients were enrolled in the study. Median age of all participants was 12 months, 61 were male and 30 were female. Stapled anastomosis was performed in 21 patients, 70 patients underwent hand-sewn anastomosis and therefore served as the control group. Demographic details of the groups can be found in Table 1.

3.2. Operative times

The overall median operative time in the stapled group was significantly shorter than in the hand-sewn group [82.5 (44–218) minutes versus 147 (52–381) minutes, $p < 0.001$), as seen in Fig. 1.

When considering only those cases that underwent stoma closure combined with other procedures (including anorectoplasty ($n = 12$), pull-through for Hirschsprung disease ($n = 15$), inguinal hernia repair ($n = 7$), gastrostomy ($n = 5$), abdominal wall hernia repair ($n = 4$), circumcision ($n = 3$), serial transverse enteroplasty ($n = 2$), and others ($n = 8$), there was no difference in mean operating time between stapled and handsewn anastomosis ($p = 0.3$).

3.3. Hospital stay

Using a stapler was associated with a significantly shorter hospital stay than handsewn anastomosis [6 (2–20 days) versus 17 (range 3–52) days, $p < 0.001$), respectively (Fig. 2).

3.4. Post-operative commencement of feeding

Patients in the miniature stapler group started feeding earlier after surgery than those in the handsewn group [2 (1–6) days versus 4 (1–24) days, $p = 0.001$] (Fig. 3).

Table 1
Demographic information of both groups.

Characteristic	Stapled ($n = 26$)	Handsewn ($n = 76$)	p
Age in months (median [range])	12 [2–24]	13 [2–29]	0.88
Sex (male/female)	15/11	52/23	0.3
Indications for enterostomy (n)			0.92
- NEC	7	15	
- Anorectal malformation	7	22	
- Hirschsprung	5	6	
- Volvulus	1	8	
- Small bowel atresia	0	7	
- Peutz-Jegher's syndrome.	1	0	
- Meconium ileus.	3	6	
- Focal intestinal perforation	2	7	
- Small bowel obstruction, unclear etiology	0	5	
Stoma closure as single procedure	12	28	0.17
Stoma closure as part of other procedures	9	42	

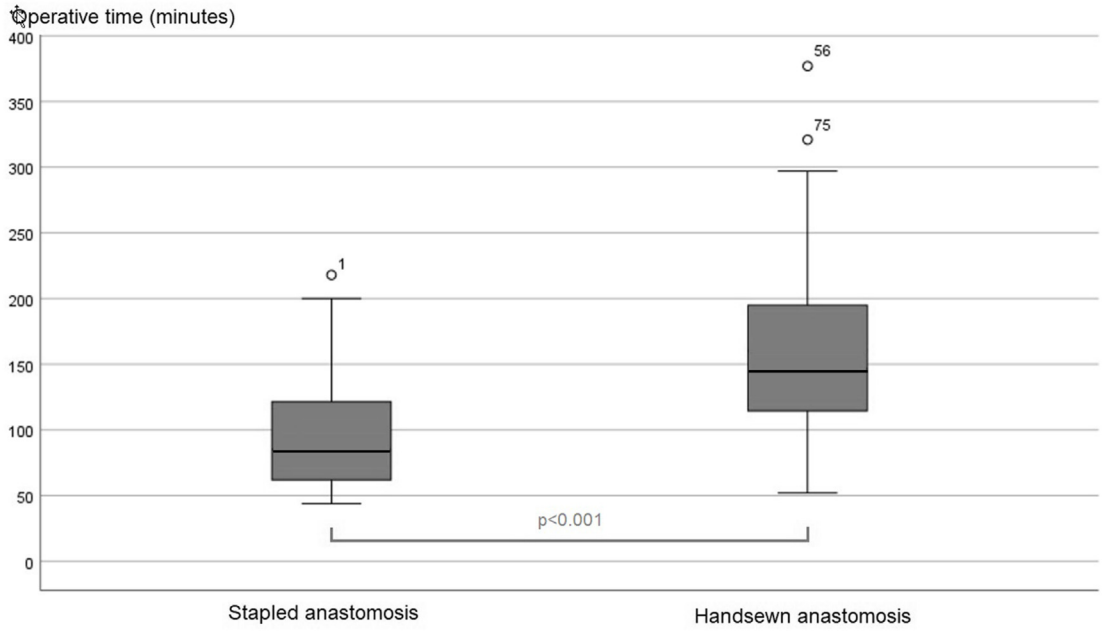

Fig. 1. Comparison of operative time between stapled (left) and handsewn (right) anastomosis.

3.5. Complications

There was no statistical difference in the complication rate between the two methods (Fig. 4). However, all cases that needed reoperation ($n = 9$ cases) were in the hand-sewn group. There were no leaks in our series, and there was no mortality.

3.6. Follow-up

Follow-up was performed for a minimum of 1 year after the enterostomy closure (range 1–6 years) by reviewing the electronic medical records. Follow-up was available for all patients included in this study.

4. Discussion

To our knowledge, this is the largest study comparing enterostomy takedown using the novel 5 mm miniature stapler to the conventional handsewn technique. The only other report on the clinical use of the 5 mm miniature stapler for intestinal anastomosis is a case series of 6 anastomoses in 5 patients [7], without a control group.

Stapled intestinal anastomosis was first described in the western literature by Steichen in 1968 [8]. Since then, staplers have been used increasingly in adults for bowel anastomosis, including enterostomy takedown, for which reduced operative time and morbidity have been reported [9]. These benefits have been confirmed in adult patients in multiple subsequent studies in terms of bowel obstruction [10] and leaks [11].

As early as 1995, staplers have been described for bowel anastomosis in pediatrics [12]. However, up to about 10 years ago, these staplers were at least 10–12 mm in diameter, and therefore inappropriate for the use in small infants. Studies on the use of these larger staplers in children have produced conflicting results. While there was no difference between stapled and handsewn anastomosis in one retrospective study on 72 patients under 5

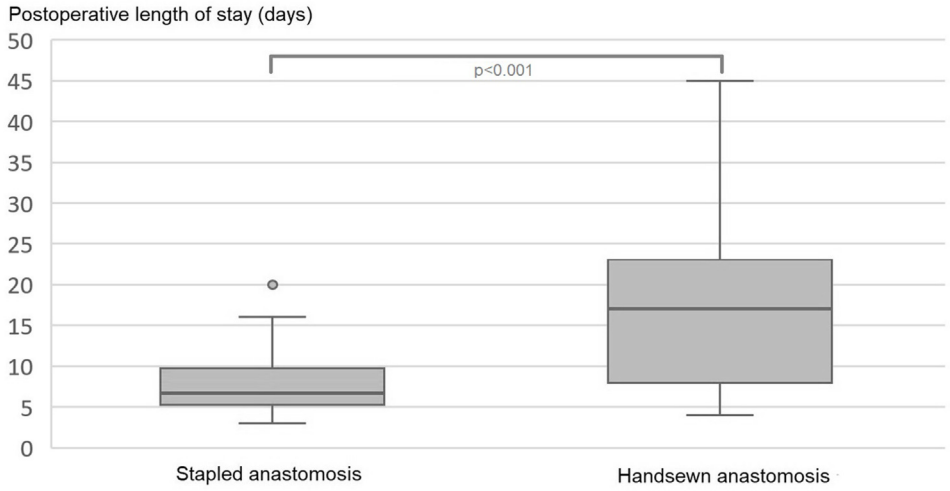

Fig. 2. Comparison of postoperative length of stay between stapled (left) and handsewn (right) anastomosis.

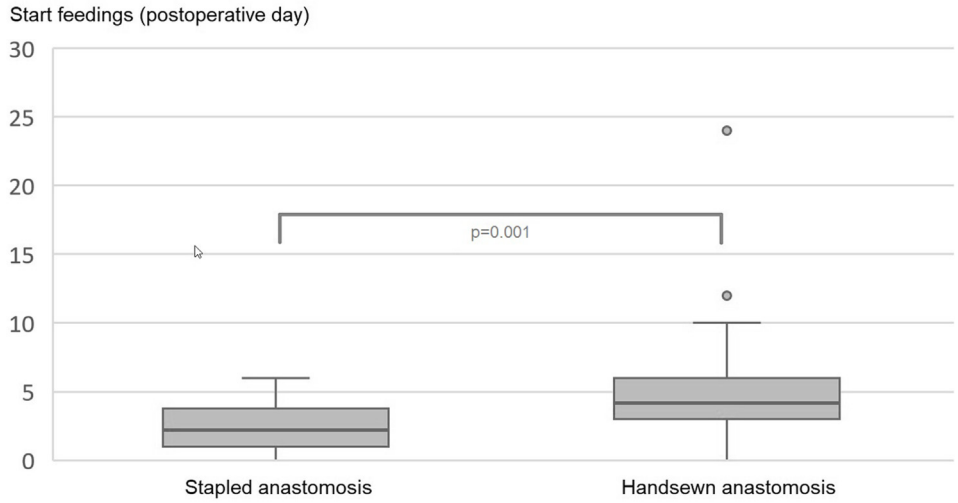

Fig. 3. Time to commencement of feeds after stapled (left) versus handsewn (right) anastomosis.

years of age [13], while a recent systematic review of 4 studies showed lower operating times and similar complication rates for stapled anastomosis in children younger than 7 years [2].

Adult-size linear staplers usually lay down 3 rows of staples on each side and cut in between. The size (length) of the staples can be chosen according to the case and is usually color-coded. For example, one company offers magazines in grey (0.75 mm), white (1.0 mm), blue (1.5 mm), and green (2.0 mm). Other technology today incorporates staples of different size in one magazine to provide good tissue purchase on the outside of the staple load (longer staples), and shorter staples for improved hemostasis towards the central cutting blade.

The miniature stapler used in this study lays down 2 rows of staples over a length of 2.5 cm. The staples are certified to close a tissue width of 0.75–1.0 mm [14]. In our experience, it is important to give the stapler time to compress the tissues for at least 20–30 s before activating the fire mechanism, so that the tissue can desiccate to a thinner caliber and thereby allow for a secure seal. The stapler should not be activated if it does not engage with a "click" upon compression of the tissue.

Our study indicates potential advantages of using a miniature stapler for enterostomy takedown in infants and toddlers, mainly in the form of shorter operative times, earlier start of postoperative feeding, and shorter length of stay. The disadvantage of using a stapler is cost (in our center, the stapler costs between 500 and 700 Euros, with a reload costing around 300 to 400 Euros).

The main limitation of our study is a possible selection bias due to lack of randomization. The control group consisted mainly of historic controls who underwent handsewn stoma takedown before the introduction of the miniature stapler. Most of our attending pediatric surgeons quickly adapted the miniature stapler for intestinal anastomosis in young children.

Apart from the technique of how it is performed, the anastomosis is similar. Therefore, apparent earlier bowel function and resulting earlier feeding may be the result of observer bias, particularly because the patients were not blinded.

Nevertheless, even after the introduction of the 5 mm stapler, there was a certain degree of surgeon preference for which patient underwent stapled or handsewn anastomosis. However, since the control group mainly consisted of unselected cases before the introduction of the miniature stapler, a systematic bias is unlikely.

Also, it is conceivable that the general trends in earlier postoperative feeding and discharge over the last decades impacted on the results [15]. Most of our handsewn anastomoses were performed in the first part of the study (2008 through 2015), while all stapled anastomoses were performed after the miniature stapler became available (2015 onwards). Early postoperative feeding of children with gastrointestinal malformations has been shown to be beneficial

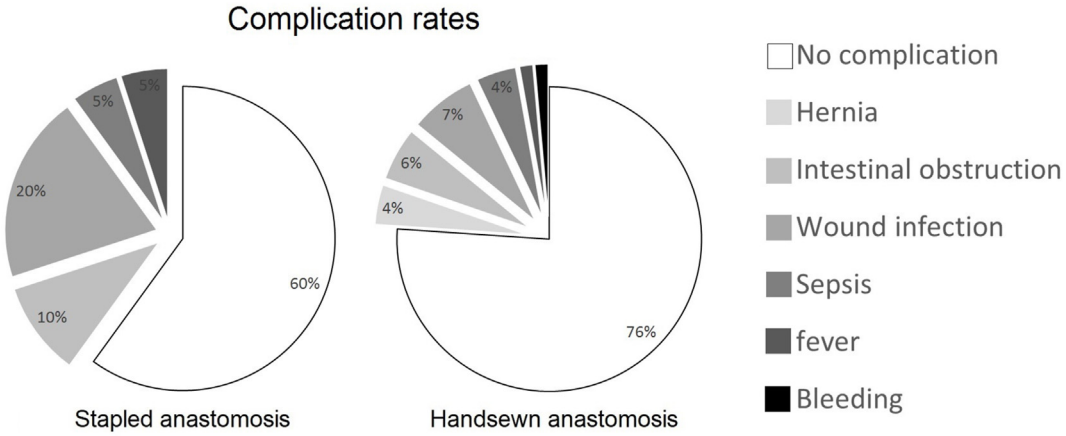

Fig. 4. Pie chart of complications of stapled (left) and handsewn (right) anastomosis.

in terms of earlier return of bowel function, lower wound infection rate, and also, shorter hospital stay [16]. Therefore, there most likely is an association between earlier feeding and shorter hospital stay.

5. Conclusions

This retrospective study shows that a 5 mm endostapler may be beneficial for enterostomy closure in infants and young toddlers in which adult staplers cannot be used because of size discrepancy between the device and the intestinal lumen. Potential benefits include shorter operative times, earlier postoperative feeding and shorter hospital stay. We believe that the stapler is particularly useful in premature neonates with co-morbidities in whom shorter operative and anesthesia times are essential. Our study shows that there is no downside in using the stapler for enterostomy takedown in young children, except perhaps the higher immediate cost of the device. Depending on the setting and charge structure, the additional cost may be offset by shorter operative times and hospital stay. A randomized, controlled trial comparing enterostomy closure using the 5 mm stapler or the conventional hand-sewn technique in infants <1 year of age should be performed to confirm or refute the findings of our study.

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