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# Clinical using of innovative biodegradable stent with extension sleeve in Ta\_tme for low rectal cancer with high risk of anastomotic leakage

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The objective of this paper is to observe and evaluate the safety and feasibility of using a degradable colorectal endoluminal stent with extension sleeve(DCESES) in patients at high risk of anastomotic leakage following low anterior resection (LAR) for rectal cancer using the transanal total mesorectal excision (Ta\_tme) technique. Six patients with low rectal cancer undergoing Ta\_tme surgery and identified as high risk for anastomotic leakage were selected. During surgery, the tumor was mobilized transanally and excised outside the anus. A suitable biodegradable stent was chosen and connected to a sterile extension sleeve. The stent was fixed with absorbable sutures 5 cm proximal to the intestinal cut end. Anastomosis was then completed at the anus, and the extension sleeve was pulled through the anus to externalize, diverting fecal matter and preventing contact with the anastomotic site. None of the six patients underwent a prophylactic ileostomy. All six patients successfully underwent Ta\_tme surgery with the implantation of the biodegradable colorectal endoluminal stent with an extension sleeve. Within 3–4 weeks postoperatively, the stent disintegrated into fragments and was expelled through the anus along with the plastic sleeve. All patients experienced no significant perianal discomfort, anastomotic leakage, anastomotic stricture, or other complications during the perioperative period. Fecal diversion using a biodegradable stent with an extension sleeve in high-risk patients for anastomotic leakage following Ta\_tme is safe and feasible. This approach effectively prevents complications such as anastomotic leakage and stricture during Ta\_tme, avoiding the need for prophylactic ileostomy and its associated complications, thereby reducing patient suffering, saving medical resources, lowering medical costs, and improving patient quality of life.

**Keywords** Low rectal cancer, Biodegradable stent with extension sleeve, Transanal total mesorectal excision (Ta\_tme)

Anastomotic leakage is a serious complication following rectal cancer surgery, leading to infections and various severe consequences, especially with a higher incidence after transanal total mesorectal excision (Ta\_tme)<sup>1,2</sup>. Poor perioperative glycemic control, obesity, preoperative neoadjuvant chemoradiotherapy, and low albumin levels are considered high-risk factors for anastomotic leakage after Ta\_tme. Prophylactic ileostomy can effectively reduce the incidence and severity of anastomotic leakage after low anterior resection for rectal cancer, and is currently a widely adopted method to prevent postoperative anastomotic leakage<sup>3,4</sup>. However, patients with a prophylactic ileostomy need to live with the stoma for an extended period, which can significantly inconvenience their lives. Additionally, the stoma may lead to various complications such as dermatitis, retraction, necrosis, and parastomal hernia. Prophylactic ileostomy and its reversal surgery entail medical costs, and the reversal can become challenging due to intestinal adhesions, or narrowing or closure of the anastomotic site at the anus. In some cases, permanent stoma formation may occur, severely diminishing the patient's quality of life. Currently,

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a biodegradable intestinal stent made from biocompatible materials is available. Clinically, it is mainly used for sutureless intestinal anastomosis and prophylactic ileostomy, with preliminary applications showing promising results<sup>5–8</sup>. The application of this biodegradable stent avoids the need for a long-term ileostomy and its reversal surgery, addressing some of the issues associated with prophylactic ileostomy. However, it also introduces some new challenges: Firstly, its placement requires an additional abdominal incision, increasing patient discomfort and additional medical costs; Secondly, the laparotomy and intestinal incision and suturing might lead to complications like intestinal adhesions and bowel obstruction; Thirdly, the site of fecal diversion is quite distant from the anastomotic site at the anus. the intestinal segment between the ileal stent blockade and the rectoanal anastomosis continues to secrete mucus, which can contaminate the anastomosis and even lead to anastomotic leakage, resulting in suboptimal diversion effectiveness. To address these shortcomings, we modified the lumen of the biodegradable stent by binding it with a sterile rubber extension sleeve using sutures, aiming to achieve the following effects: Firstly, after the tumor is mobilized and excised transanally in Ta\_tme surgery, the stent with the sleeve is fixed 5cm proximal to the tumor's proximal end outside the intestinal lumen with absorbable sutures, ensuring proper tension. The anastomosis is then completed at the anus, and the extension sleeve is pulled out through the anus. Before the stent disintegrates, the extension sleeve completely isolates the intestinal contents from the anastomotic site, thus avoiding a prophylactic ileostomy and achieving complete fecal diversion, reducing the incidence of anastomotic leakage; Secondly, allowing feces to pass through the anus as soon as possible also helps to restore anal function sooner, reducing the likelihood of anastomotic stricture or closure; Thirdly, the stent is placed during the Ta\_tme surgery, eliminating the need for an additional laparotomy. Now the application of this approach in the 6 patients is reported in the following.

Materials and methods  
General information

A retrospective analysis was conducted based on data from 6 rectal cancer patients who underwent Ta\_tme using a degradable colorectal endoluminal stent with extension sleeve at the general surgery department of our hospital from August 2023 to September 2023. The cohort included 4 males and 2 females, with an average age of 64.0±5.8 years (range: 53–70 years). Preoperative colonoscopy biopsy confirmed rectal cancer in all cases, with tumors located less than 5 cm from the anus and deemed suitable for sphincter preservation based on preliminary examinations. Routine chest CT, abdominal CT with contrast enhancement, and liver MRI were performed to exclude distant metastases in the chest and abdomen. All patients were at high risk for anastomotic leakage post-Ta\_tme: According to the AJCC guidelines, 4 patients underwent neoadjuvant chemoradiotherapy preoperatively, and 1 patient had comorbidities including hypertension, coronary heart disease, coronary stent implantation, and diabetes. All underwent Ta\_tme surgery at our hospital, with intraoperative placement of the biodegradable stent with extension sleeve. No conversion to open abdomen surgery or other fecal diversion methods were used.( We confirm that all methods were performed in accordance with the relevant guidelines and regulations by including a statement in the methods section to this effect.) Clinical data of these patients are shown in (Table 1).

Case no.		1	2	3	4	5	6
Gender		Female	Male	Female	Male	Female	Male
Age		69	53	64	70	54	60
BMI		22.2	24.7	20.2	29.2	19.2	28.4
History of diseases		None	Hypertension	None	Hypertension, coronary heart disease, coronary stent implantation	Hypertension	Lung cancer
Operative Time (min)		215	335	195	280	225	265
Intraoperative Blood Loss (ml)		100	50	200	100	200	400
Tumor location and size(cm)	Distance from tumor to anal margin (cm)	3	4	6	4	4	4
	Largest tumor diameter (cm)	1	3	3	3	1.5	4
	Distance from anastomosis to anal margin (cm)	1	2	3	2	2	2
Time to stoma closure (days)		27	27	19	24	24	24
Hospital stay (days)		11	18	14	18	15	19
Postoperative adjuvant chemotherapy		Done	Not done	Done	Not done	Done	Done
Pathological stage		T2N1M0	T1N0M0	T2N0M0	T1N0M0	T0N0M0	T2N3M0

**Table 1.** Clinical data of the 6 patients undergoing laparoscopic assisted radical resection of rectal cancer with stent method for intestinal diversion.

## Study methods

This study was approved by the Medical Ethics Committee of Second Affiliated Hospital of Army Medical University PLA (Approval number: Device Clinical Trial 158-02). All patients voluntarily chose Ta<sub>tme</sub> surgery with the insertion of the biodegradable stent with extension sleeve.

### *Indications and contraindications*

#### Indications

- (1) Pathologically confirmed primary solitary rectal cancer without distant metastases;
- (2) Planned Ta<sub>tme</sub> procedure;
- (3) Age between 18–80 years, regardless of gender;
- (4) Nutritional risk screening score  $\leq 2$  points;
- (5) Subjects voluntarily participate in this clinical study and sign an informed consent form for the surgery.

#### Contraindications

- (1) History of rectal surgery;
- (2) Familial adenomatous polyposis, hereditary non-polyposis colorectal cancer;
- (3) Active Crohn's disease or active ulcerative colitis;
- (4) Acute cardiovascular or cerebrovascular events within the past 6 months (e.g., unstable angina, acute myocardial infarction);
- (5) Continuous use of corticosteroids within the past month;
- (6) Pregnant or planning to become pregnant women, breastfeeding women;
- (7) Severe mental disorders;
- (8) Severe complications that cannot tolerate surgery or require emergency surgery;
- (9) Discovery of multiple rectal tumors, distant metastases, or inability to achieve R0 resection during surgery;
- (10) Not undergoing laparoscopic anterior resection of rectal cancer due to conversion to open surgery or other surgical methods.

#### *Surgical method*

The surgeries for all six low rectal cancer patients were completed by the same medical team.

Under general anesthesia with endotracheal intubation, the patients were positioned in the lithotomy position.

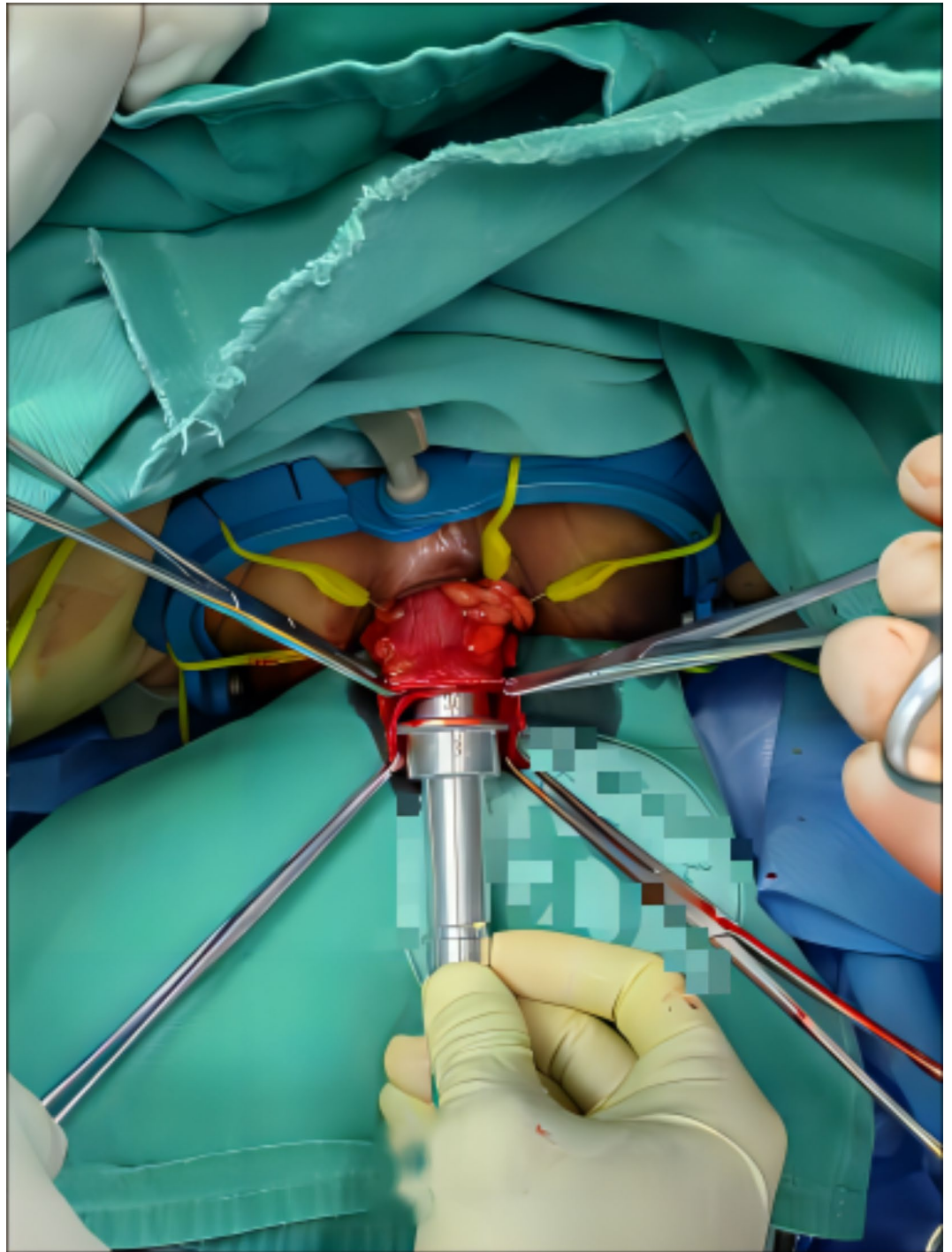
**Abdominal operation** Five trocars are placed above the umbilicus, to the left and right of the umbilicus, in the left upper abdomen, and in the right lower abdomen. Under laparoscopy, following the TME principle, the peritoneum on the right side of the inferior mesenteric vessel root was incised, the inferior mesenteric artery and vein were mobilized, ligated with absorbable clips, and divided with an ultrasonic scalpel. The rectum was mobilized to the peritoneal reflection and adequately freed to the plane of the levator ani muscle.

**Transanal operation** Depending on the tumor's location, the following steps were taken: A port was implanted transanally, and the abdomen was insufflated to a pressure of 12mmHg using an insufflator (manufacturer: ConMed, USA, model: AS-iFS2). A, for tumors 3–5 cm from the dentate line, purse-string sutures were placed under direct vision, followed by the placement of the operating platform; B, for tumors 1–3 cm from the dentate line, purse-string sutures were first placed under direct vision, then 1 cm distal to the purse-string, the anal canal was then incised, the intersphincteric space was dissected, and finally, the operating platform was placed. With the help of laparoscopy, the resection margin was circumferentially marked 1 cm proximal to the purse-string suture site, and the mucosal layer, submucosal layer, and muscular layers (inner circular and outer longitudinal) were sequentially incised using an electrotome or ultrasonic scalpel. The Ta<sub>tme</sub> procedure progresses upwards through four anatomical spaces: A, the intersphincteric space; B, the suprapubic space; C, Denonvilliers' fascia space; D, the presacral space. Finally, the abdominal and transanal teams converged, completely mobilizing the rectum and tumor.

**Specimen extraction** After adequately mobilizing the mesentery of the sigmoid colon and the proximal colon, the transanal operating platform was retracted. A protective sleeve was inserted into the incision, and the mobilized bowel was pulled out through the anus. Whether the specimen is extracted transanally or transabdominally, it is essential to trim the mesentery according to the principles of radical rectal cancer surgery, transecting the bowel at least 10 cm proximal to the tumor lesion, and cleaning the pelvic and abdominal cavity.

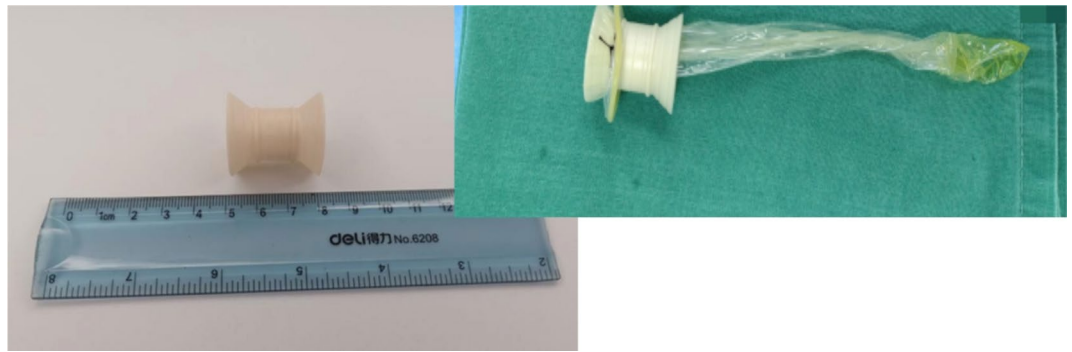
**Implantation of the stent with extension sleeved** Biodegradable Stent (Batch number: Device Clinical Trial 20190903-15).

The inner diameter of the proximal bowel was measured with a columnar ruler (as shown in Fig. 1). A suitable-sized stent was chosen and connected to a sterile extension sleeve (as shown in Fig. 2). The biodegradable stent was placed inside the proximal bowel 5 cm from the cut edge (as shown in Fig. 3). Using absorbable sutures, the stent was fixed at the predetermined position in the bowel through the mesorectum from outside the bowel lumen (as shown in Fig. 4), ensuring proper tension. The proximal bowel was then pushed back into the pelvis through the anus.



**Fig. 1.** Measurement of the intestinal cavity diameter using a columnar ruler.

**Reconstruction of digestive tract** If the distal rectal incision is more than 2 cm from the dentate line, the digestive tract can be reconstructed using a stapler. The procedure is as follows. The anvil head is placed in the proximal bowel, and after completing a full-thickness purse-string suture at the anal side, the purse-string is tightened around the central rod of the anvil head, which has been reintroduced into the pelvis. After ensuring there is no torsion in the bowel, the stapler is docked with the external central rod to complete an end-to-end anastomosis, and the incision should be inspected. If the anastomosis is within 2 cm of the dentate line, a continuous full-thickness end-to-end manual anastomosis is performed under direct vision using 3/0 absorbable suture (as shown in Fig. 5).



**Fig. 2.** Connection of the extension sleeve with the stent of appropriate model.

**Sterile plastic sleeve extraction** The sterile protective sleeve was passed through the anastomosis and extracted through the anus (as shown in Fig. 6). The distal end of the sterile protective sleeve was then cut (as shown in Fig. 7), and the surgery was completed.

#### *Postoperative care and follow-up methods*

Postoperatively, patients were fed a semi-liquid, low-residue diet. The quantity and nature of the output from the diversion tube were monitored daily, along with the patient's temperature, abdominal signs, and routine blood tests. Follow-ups were scheduled for the 14th, 21st, 28th days postoperatively and one month after tube removal. In addition to routine blood and biochemical parameters, the drainage tube was removed between 7 and 9 days postoperatively if there are no abnormal findings such as anastomotic leakage. No patients experienced complications such as anastomotic stricture or leakage. If postoperative pathological examination reveals lymph node metastasis or high-risk factors for recurrence, adjuvant chemotherapy is administered. Postoperative anastomotic status was checked monthly, with regular follow-ups every three months for postoperative rectal cancer.

### **Statistical methods**

Quantitative data with a normal distribution are presented as mean  $\pm$  standard deviation ( $\bar{x} \pm s$ ), and categorical data are expressed as frequency and percentage.

### **Surgical method**

The surgeries for all six patients with low rectal cancer were performed by the same medical team. The Ta<sub>tme</sub> procedure was followed for the mobilization of rectal tumors and lymph node dissection, with the specimen extracted through the anus, and the proximal end of the bowel transected, similar to the conventional Ta<sub>tme</sub> method (omitted here). After tumor excision, the inner diameter of the proximal bowel was measured, the appropriate-sized stent was chosen and connected to a sterile extension sleeve (as shown in Fig. 2), and the sleeved biodegradable stent was placed 5 cm from the cut edge inside the proximal bowel. The stent was fixed at the predetermined position in the bowel using absorbable sutures. The proximal bowel was pushed back into the pelvis through the anus, and after inserting the stapler anvil, anastomosis was completed with the distal anal canal or the proximal end of the bowel was directly sutured to the anal canal. The sterile extension sleeve was passed through the anastomosis and extracted through the anus, with the end of the sleeve cut off to complete the surgery (as shown in Fig. 8).

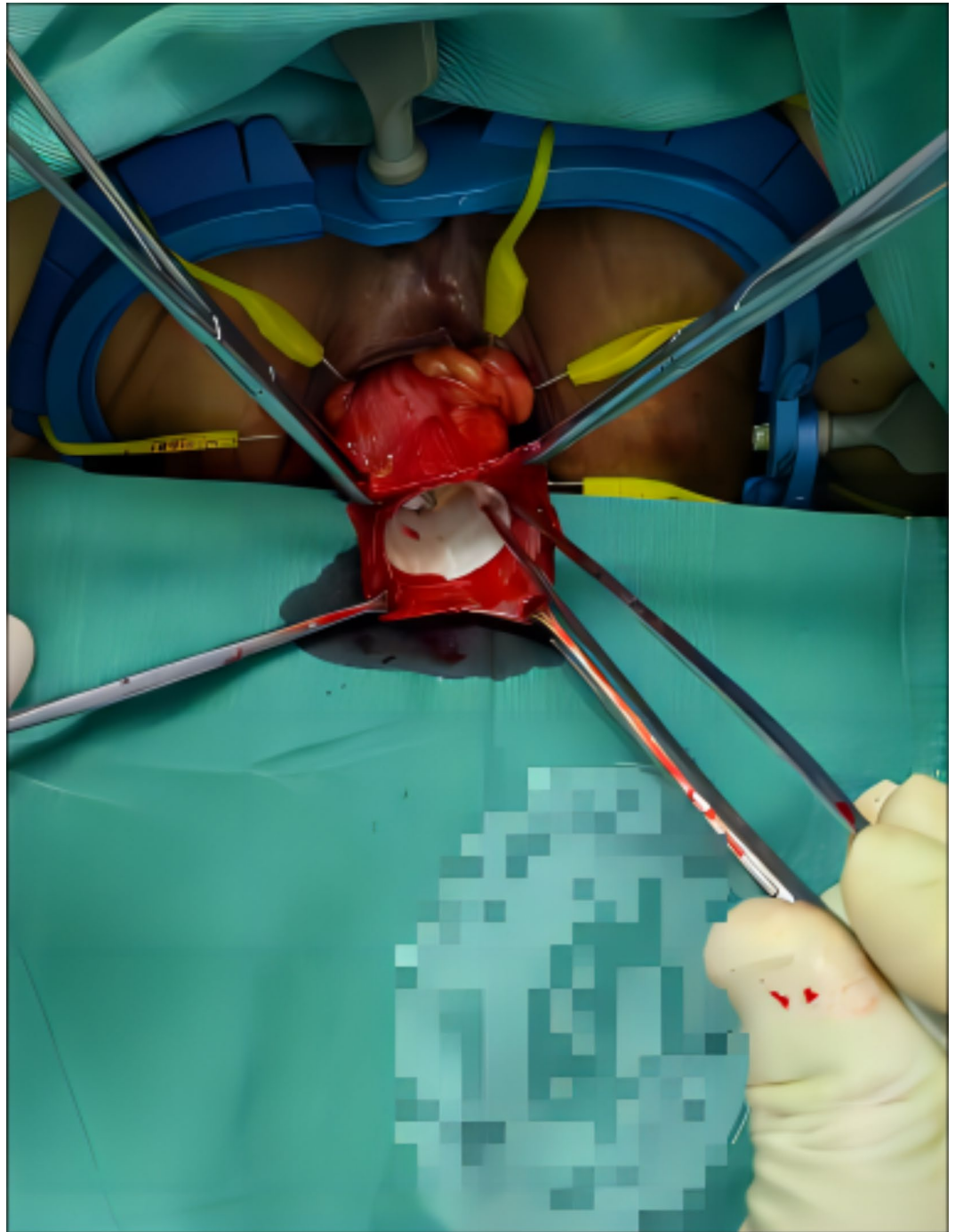
### **Methods for postoperative care and follow-up**

After the restoration of gastrointestinal function, patients were fed a liquid or semi-liquid, low-residue diet. The volume and nature of the output from the diversion sleeve were monitored daily, along with the observation for any obstruction or displacement of the diversion tube. The fragments of the disintegrated stent and plastic sleeve are expelled through the anus as the stent disintegrates.

### **Results**

The mean operation time was  $252.5 \pm 51.4$  min (range: 195–335 min), intraoperative blood loss was  $175 \pm 125.5$  ml (range: 50–400 ml), and total hospital stay was  $15.8 \pm 3.1$  days (range: 11–19 days). There were no significant perianal discomfort, anastomotic leaks, or other complications postoperatively. The tumor was measured intraoperatively to be  $4.2 \pm 1.0$  cm (range: 3–6 cm) from the anal verge, the largest tumor diameter was  $2.6 \pm 1.1$  cm (range: 1–4 cm), and the anastomosis was  $2.7 \pm 1.2$  cm (range: 2–5 cm) from the anal verge. Postoperative pathological examination showed: 6 cases of moderately differentiated adenocarcinoma, 1 case of stage T0, 2 cases of T1, and 3 cases of T2; the number of lymph nodes harvested was  $1 \pm 2$  (range: 0–5 nodes), with 2 positive cases and 4 negative cases of lymph node metastasis.

The biodegradable stent used in our study is mainly composed of a hollow cylindrical conduit with two gradually widening bell-shaped openings at each end, with protruding rings near the bell-shaped openings for tying the intestinal loops. The stent gradually disintegrates into fragments in the intestinal tract over about 3–4

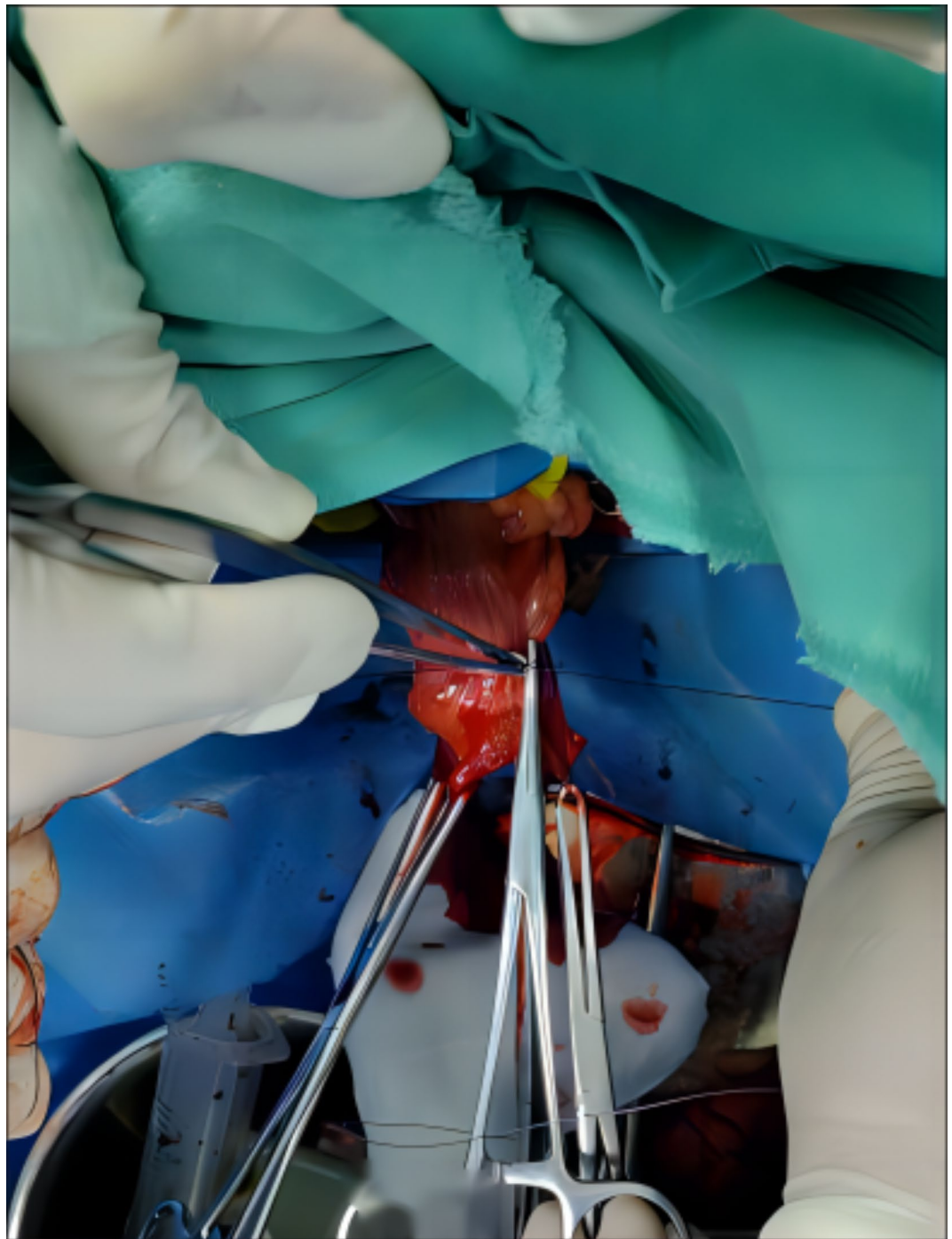


**Fig. 3.** Placement of the modified stent into the proximal bowel cavity.

weeks and is excreted with the feces, leaving no foreign bodies in the body. Additionally, we combined the sterile extension sleeve with the stent. The protective sleeve is made of natural rubber, soft in texture, and shaped like a hollow cylinder with a ring-shaped protrusion at one end. It can completely isolate the intestinal contents and has good extensibility, mainly serving to divert the intestinal contents outside the body.

All 6 patients successfully underwent Ta<sub>tme</sub> with stent placement, without performing a prophylactic ileostomy. The plastic sleeve was expelled through the anus within a month postoperatively, with an average expulsion time of  $24.2 \pm 2.9$  days (range: 19–27 days). All patients were followed up regularly for 3 to 4 months. No complications such as intestinal obstruction, anastomotic leakage or anastomotic stenosis occurred in all patients during the follow-up.

This method not only retains the many advantages of Ta<sub>tme</sub> treatment for low rectal cancer but also avoids the postoperative anastomotic stricture common with current Ta<sub>tme</sub> procedures. It maximizes the preservation

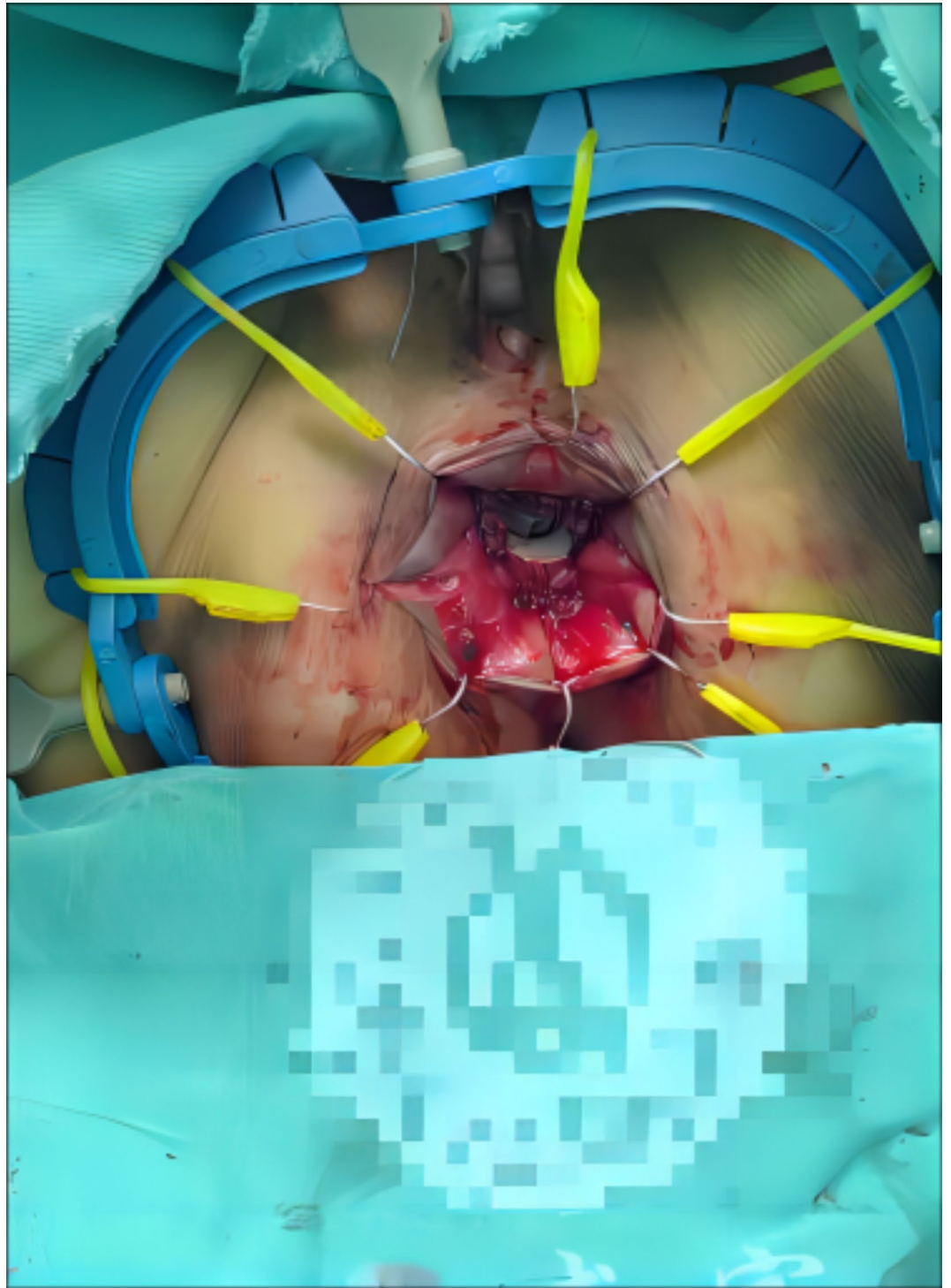


**Fig. 4.** Fixation of the stent at 5cm from the end of the bowel.

of anal function while achieving good oncological outcomes, especially in avoiding prophylactic ileostomy and its reversal.

### Discussion

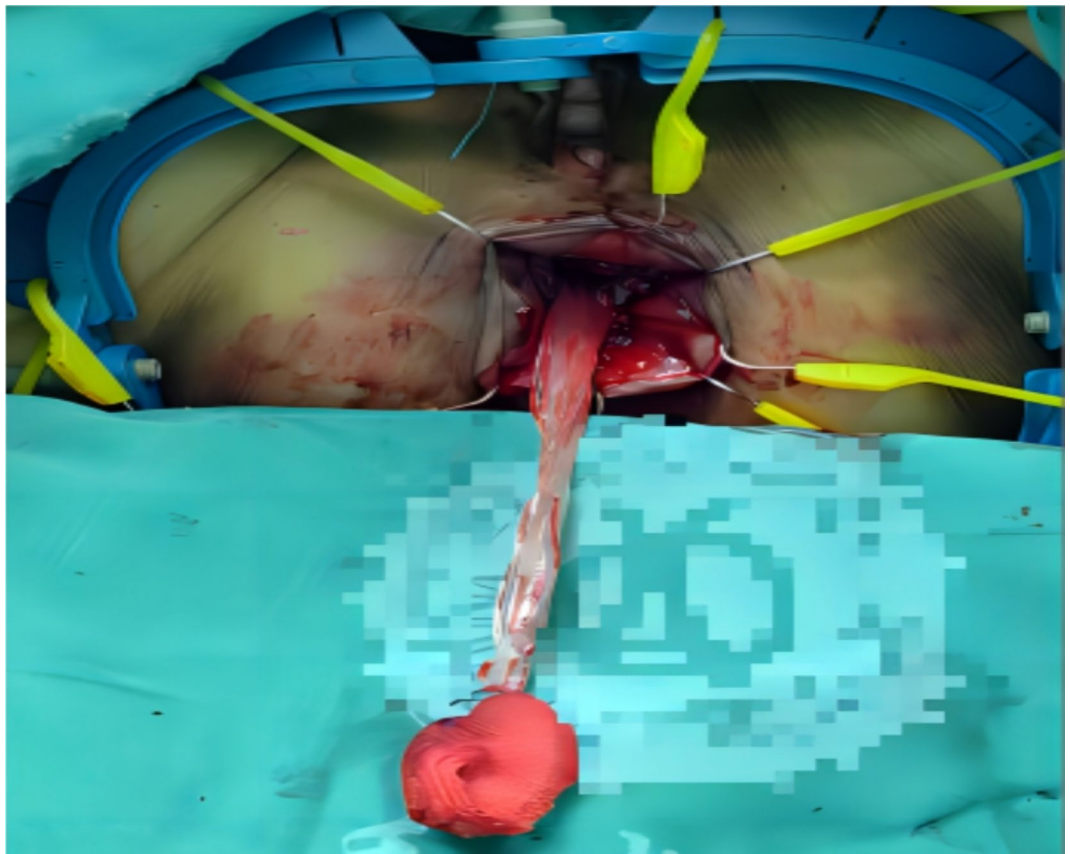
In this study, six patients who required Ta<sub>tme</sub> for rectal cancer radical surgery were treated with a disintegrating stent with an extended sleeve. The advantages of this method are: This surgical method has four major advantages: (1) fixing the stent 5 cm from the proximal end of the transected bowel segment maximizes the diversion of intestinal contents; (2) before the stent disintegrates, the extension sleeve completely isolates the intestinal contents from the anastomosis, avoiding prophylactic ileostomy and achieving complete fecal diversion, reducing the risk of anastomotic leakage; (3) allowing feces to pass through the anus as soon as possible also helps to restore anal function sooner, reducing the likelihood of anastomotic stricture or closure; (4) placing the stent



**Fig. 5.** Completion of the anastomosis based on the patient's actual situation.

during Ta<sub>tme</sub> surgery without additional laparotomy avoids potential complications from it, such as intestinal adhesion and obstruction, alleviating patient discomfort and reducing medical costs. Finally, achieving a “one-stop sphincter-preserving” Ta<sub>tme</sub> surgery.

In recent years, with the increasing incidence of rectal cancer and the use of preoperative neoadjuvant therapy, more patients with low rectal cancer have had the opportunity to undergo sphincter-preserving surgery<sup>9–11</sup>. However, in cases where the tumor is large, positioned low, in obese patients, or with a narrow pelvis, performing sphincter-preserving surgery through standard laparoscopic low anterior resection (LAR) is extremely challenging<sup>12–14</sup>. Difficulties in mobilizing the rectum and tumor from above and transecting the distal bowel can be compounded by excessive forceful traction, which may result in tumor or bowel rupture,



**Fig. 6.** Extraction of the extension sleeve through the anus past the anastomosis.

challenging the sterility and no-tumor principles crucial in oncological surgery. The Transanal Total Mesorectal Excision (Ta\_tme) was first reported by Sylla et al. in 2010 under laparoscopic assistance<sup>15</sup>.

Ta\_tme, a further development and innovation based on the TME by colorectal specialists worldwide, is hailed as a “revolutionary innovation” in the surgical treatment of rectal cancer. For patients with large tumors, low tumor positions, obesity, or a narrow pelvis, Ta\_tme is increasingly favored by experienced surgeons as an alternative to the total mesorectal excision (TME) approach<sup>16–18</sup>. Compared to traditional laparoscopic TME, Ta\_tme offers better exposure of the distal mesorectal space, operability in narrow pelvises, and precise determination of the distal resection margin. These advantages improve surgical quality, minimize collateral damage, and preserve the patient’s anus while ensuring oncological radicality. Although Ta\_tme can preserve the anus, anastomotic leakage and stricture are common postoperative complications. The risk of anastomotic leakage is higher, especially in male patients, or who have undergone neoadjuvant chemoradiotherapy, or have low tumor positions, or have diabetes, with reported incidences ranging from 5.9 to 18%<sup>19–21</sup>. Denmark temporarily halted this technique due to its high rate of anastomotic leakage<sup>22</sup>. Anastomotic leakage typically leads to prolonged hospital stays, reduced quality of life, the need for multiple surgeries, and even patient mortality<sup>23</sup>. To reduce the incidence of anastomotic leakage, surgical experts have been exploring and improving methods, and prophylactic ileostomy was invented, which has been effective in reducing both the incidence and severity of anastomotic leakage<sup>23</sup>.

Currently, performing a prophylactic ileostomy after Ta\_tme is a widely accepted method both domestically and internationally to reduce the risk of anastomotic leakage. Although prophylactic ileostomy effectively reduces the incidence and severity of anastomotic leakage, it also introduces new problems: patients must live with a stoma for a prolonged period, and the stoma and its complications can cause inconvenience in their lives<sup>24</sup>. In response to these issues, many scholars have innovated various techniques to reduce complications like anastomotic fistula and stricture, such as Cai’s intestinal diversion stent, the sac rectal drainage tube, the condom connection method for intestinal bypass, and the sheathed ileostomy technique<sup>25–30</sup>. However, these have not been reported for use in Ta\_tme surgery. Cai’s intestinal diversion stent is a type of biodegradable intestinal stent that has completed medical device registration (batch number: Device Clinical Trial 20190903-15). It is a hollow cylinder slightly smaller in diameter than the intestine, with bell-shaped openings at both ends to prevent the fixing thread from slipping off. A barrier membrane inside the hollow cavity prevents intestinal contents from entering the downstream intestine. The stent is made of barium sulfate-containing polyhydroxyacetic acid and fully disintegrates within 3–4 weeks in the human body<sup>5–8</sup>. Ileostomy: After excising the rectal tumor and reconstructing the anastomosis during surgery, a segment of ileum 20 cm from the ileocecal valve is pulled out to the abdominal wall to perform a prophylactic ileostomy<sup>31</sup>. This technique avoids long-term ileostomy and

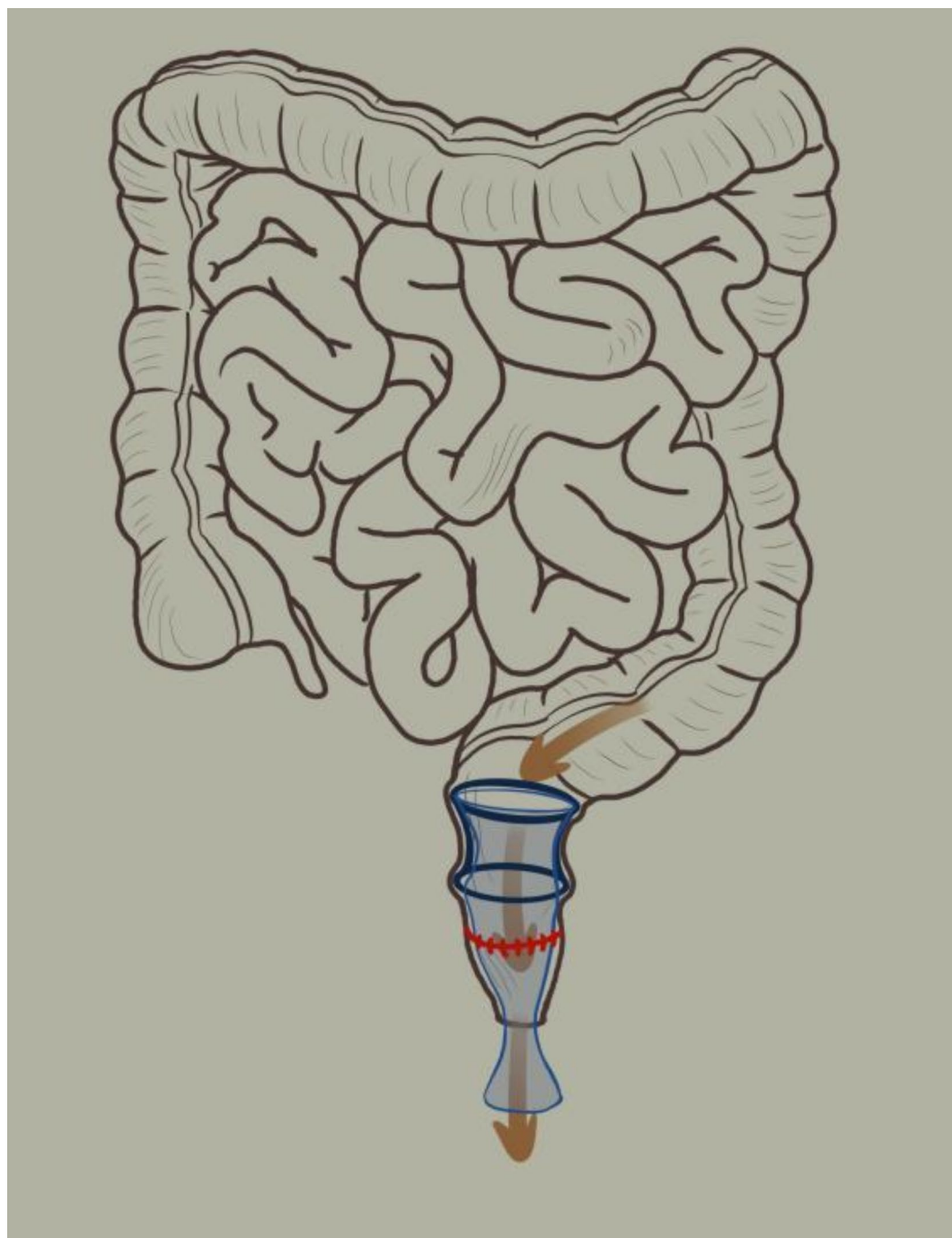


**Fig. 7.** Removal of traction aids used during the surgery.

ileostomy reversal surgery, addressing some issues of prophylactic ileostomy, but still has unresolved problems: (1) its placement requires an additional abdominal incision, increasing patient discomfort and additional medical costs; (2) the technique involves laparotomy and intestinal incision and suturing, potentially increasing the risk of complications such as intestinal adhesion and obstruction; (3) the fecal diversion site is far from the anastomosis at the anus, and the intestinal segment between the ileal stent and the anastomosis continues to secrete mucus, potentially contaminating the anastomosis and leading to leakage.

To address these issues, we made modification based on the biodegradable stent. After completing Ta<sub>1</sub>me tumor excision, we choose a stent of appropriate size based on the patient's intestinal diameter, connect it to a sterile extension sleeve, and fix the modified stent in the bowel 5 cm from the proximal end of the bowel segment. After completing the anastomosis at the anus, the extension sleeve is routed through the anastomosis and pulled out through the anus, isolating the bowel contents from the anastomotic site and diverting them externally.

However, the number of cases currently implemented in this method is not large, and it is only a single-center observational study. Our center started a prospective randomized controlled study, with 4 cases in the experimental group and 4 cases in the control group, and the experiment went smoothly. We are applying for a national multicenter prospective randomized controlled study to further test its clinical efficacy and promotion.



**Fig. 8.** Schematic diagram of the intestinal diversion surgery using the biodegradable stent with extension sleeve.

### Data availability

The data used to support the findings of this study are available from the corresponding author upon request.

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## Author contributions

Rongrong Hao: Conceptualization, data collation, statistics, manuscript writing. Wensheng Wang, Jianghong Chen, Yuanhang Ma, Yang Yang, Yunbo Li : Surgery, Follow-up visit Data curation, Formal analysis, Visualization. Zhicao Zhang, Dan Ma: Surgery, Conceptualization, Formal analysis, Funding acquisition, Project administration, Supervision, Visualization, Writing—review & editing. All authors read and approved the final version of the manuscript.

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## Declarations

## Competing interests

The authors declare no competing interests.

## Ethics approval and consent to participate

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## Additional information

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