Early experience of undertaking robotic-assisted total mesorectal excision in rectal resections, avoiding a diverting stoma: KHANS technique — a Case Series

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Funding

No funding was provided for this study

Acknowledgements

Editorial support was provided by Deborah Nock (Medical WriteAway, Norwich, UK).

Disclosures

Dr A Waqas, Dr A Anwar, Ms K Flashman, Dr S Naqvi, Dr Harper have no conflict of interest or financial ties to disclose. Dr J Khan is a proctor with Intuitive Surgical.

Ethics approval. The project was registered with the R&D department Portsmouth Hospitals NSH Trust.

Consent to participate. All patients in this study provided written consent to treatment and data capture and publication.

Authors' contributions.

Concept – JK

Materials – SS, IM

Data collection &/or processing – AW, NS, AA,

Analysis and/ or interpretation – AW, SN, JK

Literature search – NS, SS, IM, SN

Writing – AW, AA, JK

Critical review – AW, SS, IM, NS, MH, SN, NS, JK

Original paper

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Running title: Robotic total mesorectal excision

Disclosures:

JSK is a proctor with Intuitive Surgical

All other authors have nothing to disclose

Funding:

None

Synopsis:

This paper describes a new surgical technique used to reduce the need for diverting stomas in conjunction with robotic TME surgery for rectal cancer.

Abstract

Background: Anastomotic leak is a feared complication in rectal cancer surgery, and a proximal diverting stoma to protect the rectal anastomosis is used to minimize its impact. We evaluated a novel technique that uses the da Vinci® robotic platform (Intuitive Surgical) to reinforce the colorectal anastomosis and rectal staple line with sutures, and rectal resection and assessment of the anastomotic perfusion, using our Portsmouth protocol.

Methods: During robotic rectal cancer surgery, we used indocyanine green to determine the level of transection and check the vascularity of the circular anastomosis. The distal transverse staple line and circular staple line of the colorectal anastomosis were reinforced with absorbable interrupted stitches (KHANS technique – Key enHancement of the Anastomosis for No Stoma). The integrity of the colorectal/anal anastomosis was also checked using the underwater air-water leak test, with concomitant flexible sigmoidoscopy to visualize the circular staple line.

Results: Fifty patients underwent total mesorectal excision for cancer. Using the KHANS technique, weavoided a diverting stoma in all cases. One patient had a radiological leak, leading to a pelvic abscess. In 56% ofcases, the anastomosis was within 5 cm of the anal verge. Median length of stay was 5 (3-34) days, with two 30-day readmissions. No 90-day mortality or 30-day reoperations were observed.

Conclusion: The KHANS technique appears feasible, successful, and safe in decreasing the incidence of diverting stomas in rectal resections.

Key words: anastomosis; diverting stoma; rectal cancer; rectal resection; robotic-assisted surgery.

Introduction

Rectal cancer surgery is complex for a variety of patient-related, anatomical, and surgical reasons. Anastomotic leak remains one of the most feared complications, with a reported incidence that varies from 3–17% [1-4]. The main risk factors include the patient's general fitness, surgical technique, and level of anastomosis, including the number and effectiveness of stapler firings due to difficulty in stapling, proximity to the sphincter complex, operating in the narrow pelvis, and subsequent collateral damage from the use of energy sources. Systemic disorders, chemoradiation, tumor volume, and compromised blood supply [2-4] add to this extensive list of risk factors. To mitigate and minimize the risk, colorectal surgeons have opted for a proximal diverting stoma (ileostomy or a colostomy) to protect a rectal anastomosis. The temporary stoma rate after total mesorectal excision (TME) surgery varies between 70–85% [5]. Over half of patients with rectal cancers require postoperative chemotherapy, and these stomas may not get reversed until 8–12 months after surgery. Almost 20% of these patients never have their stomas reversed for various reasons [5-7]. Ileostomies are not without problems, i.e., high output stoma, stenosis, retraction, prolapse, and electrolyte imbalance, sometimes necessitating multiple admissions in hospitals and delayed discharge. Reversal of ileostomy also carries a degreeof morbidity [8].

We describe a novel technique for suture reinforcement of the colorectal anastomosis using the da Vinci® robotic platform (Intuitive Surgical, California, USA) and assessment of the anastomotic perfusion, using our Portsmouth protocol [9]. The aim of this KHANS technique (Key enHancement of the Anastomosis for No Stoma Surgery) is to reduce the incidence of anastomotic leak and the requirement for diverting stoma in roboticrectal resections. The da Vinci robotic platform offers distinct advantages for operating surgeons, including 3D vision, a stable robotic camera platform and dexterous EndoWrist instruments, and can offer further benefits when combined with our innovative technique.

The main components of the KHANS technique include accurate placement of the stapler on the rectum after perfusion assessment with indocyanine green (ICG), suture reinforcement of the transverse rectal staple line at the superior and inferior end, and anterolateral suture reinforcement of the circular staple line with interrupted sutures. The transverse staple line in the rectum after colorectal resection is 50-60 mm long, and the circular anastomosis (created using a circular stapler; Ethicon, CDH series) is 29 mm or 31 mm wide; this leaves an areaof 15-20 mm on each side of the stapler, commonly referred to as the "dog ears" [10]. These are potentially weak spots for ischemia, and can be the site of a postoperative anastomotic leak [11]. Using robotic instruments,surgeons can reinforce these weak spots by suturing over the sites and burying the weak corners, thus mitigating the risk of complications. Finally, upon completion of the colorectal anastomosis the circular staple line can be reinforced with interrupted sutures to provide an extra layer of protection for the anastomosis.

Materials and methods

Patients who underwent robotic TME for rectal cancer between 2016 and 2018 at a teaching hospital were included in this study. All patients were discussed at the colorectal multidisciplinary team meetings andreviewed by a consultant surgeon, and informed consent was obtained. Patients were eligible for inclusion ifthey had biopsy proven upper, mid, or low rectal cancers necessitating restorative anterior resection. Patients were excluded if they had poor functional status, ASA IV, metastatic disease, permanent colostomy, poor response to long-course chemoradiotherapy (tumor regression grade 4/5), and ultralow resection (coloanal anastomosis) +/- intersphincteric resection. Patients data were collected prospectively on an ethically-approved colorectal database, and retrospectively reviewed. Preoperative diagnostics included patient demographics, tumor histology and staging, including a computed tomography (CT) scan of the chest, abdomen and pelvis and magnetic resonance imaging (MRI) of the pelvis. An intraoperative sigmoidoscopy was performed to determine the distance of the height of tumor and to choose the level of rectal transection, with rectal irrigation routinely performed with water. Clinical and oncological outcomes were recorded, including anastomotic leak – categorized as a palpable or radiological defect in the anastomosis and subdivided into clinical leak (necessitating a return to theater with severe sepsis) and radiological leak (detected on a CT scan and managed with antibiotics and/or a radiologically-inserted drain). Postoperative ileus was defined as a lack of bowel activity (flatus or feces) for more than 72 hours, with abdominal distension. Postoperatively, patients were managed in an enhanced recovery program, with a liquid diet for the first 48 hours and regular laxative(lactulose 10 ml twice a day) started from the third postoperative day. This case series has been reported in line with the PROCESS criteria [12].

Surgical technique

Robotic TME was performed with single docking of a da Vinci (Si/X) surgical system from the left hip. All patients had preoperative bowel preparation using two sachets of Picolax® (Ferring Pharmaceuticals). Standard oncological resection was carried out using the single docking robotic TME technique described previously [13]. Port placement was as shown in Fig. 1 for the Si and X systems. Before transection of the rectum, ICG was used to identify perfusion of the rectal tube by administering an intravenous bolus of ICG (3 ml, 7.5 mg) prior to stapling (Fig. 2), followed by the operating surgeon and assistant agreeing on the optimal level of transection after ICG immunofluorescence. **Small bowel prefusion was used as a control and adequacy of perfusion was decided by comparing the immunofluorescence at site/level of transection with the immunofluorescence in the normally perfused bowel loops.** Rectal transection was performed using robotic stapler (Sureform), with accurate placement on the rectal tube after ICG assessment (Fig. 3). Subsequently, 3/0 interrupted vicryl sutures were used to bury the corners of the transverse staple line at both ends, as shown in Fig. 4. The specimen was extracted through a supra pubic wound extraction site (measuring approximately 4–5 cm, depending on the tumor size), using an Alexis wound protector, followed by **selection of proximal transection level based upon quality** of the proximal marginal artery bleed,and **then** insertion of the anvil of a CDH stapler. A colorectal anastomosis was fashioned under direct vision usingthe robotic arms (Fig. 5a-c). Traditionally, the engagement of the anvil with the spike of the CDH stapler can be a difficult task, especially in a male patient with low anastomosis; however, robotic instruments make this step fairly straightforward and quick. Further ICG assessment as described above was repeated at this stage to assess both proximal and distal segmental perfusion. Circular anastomosis was then reinforced with interrupted 3/0 vicryl sutures, with a median of 8-10 sutures required to reinforce the anastomosis anterolaterally (Fig. 5d). Carewas taken not to damage the mesentery and colonic blood supply posteriorly, and this was enhanced by the use of the clear view and EndoWrist instruments, which facilitate accurate placement of these sutures without tension at the anastomosis. Finally, an underwater air leak test and flexible sigmoidoscopy were performed (Fig.6). This confirmed a healthy and patent anastomosis with good mucosal vascularity and no air leak. This technique is shown in the accompanying video clip with the exact steps of the procedure (V1).

Results

This technique of robotic TME with suture reinforcement of the staple line and ICG assessment of the colonic perfusion was used successfully over 3 years in 50 patients (32 males; median BMI 27 kg/m^2) (Table 1). The majority of patients were ASA grade I and II, with a median age of 65 years; one 91-year-old lady had an anterior resection and was successfully discharged home on day 5. Twelve patients had previous abdominal surgery. The median blood loss was 10 ml, and the median operating time was 230 minutes. The anastomosis was low (1–5 cm from the anal verge) in 56% of patients, and higher (5–10 cm from the anal verge) in 44% of patients. **In three patients the site of rectal transection was adjusted based on perfusion results. There was ischemia of proximal colon in one case requiring further resection of 5 cm segment intra-operatively**. The median hospital stay was 5 days, and the median time to return of bowel function (feces) was 3.5 (range 2–7) days. There were no conversions to open surgery, and the median lymph node harvest was 20 (range7–40). One patient had a positive circumferential resection margin. All cancers were adenocarcinomas.

There was no 30- or 90-day mortality, and none of patients required a return to theater or had a major anastomotic leak. One patient had a postoperative pelvic collection on the CT scan, which was managed with a course of antibiotics. Another 27-year-old patient had a radiological anastomotic leak, but was clinically stable with minimal symptoms and was managed conservatively with antibiotics and radiological drainage, with complete resolution of abscess. Two patients were readmitted within 30 days due to postoperative pain and vomiting. They were assessed using cross-sectional imaging; no intra-abdominal sepsis was identified and they were successfully discharged in 48 hours .

Discussion

The complexity of minimally-invasive rectal cancer surgery, coupled with the higher incidence ofcomplications, especially anastomotic leak, continues to add to the morbidity and mortality of patients [1-4]. Colorectal anastomosis below the level of the peritoneal reflection carries a higher risk of anastomotic leakage **as compared to a higher anastomosis**. [4,14,15]. Colorectal surgeons rely significantly on linear and circular staplers to fashion their anastomoses. While most minimal access surgeons will accept two firings of a linear stapler, stapling in the lower pelvis can be challenging, sometimes requiring 3–4 firings of the liner stapler to achieve complete rectal division. There isa concern that with an increased number of stapler firings to divide the rectal tube, there is an increased risk of anastomotic leak [4,16,17]. Use of a robotic stapler can reduce the number of firings needed to transect the rectum [18].

In our study, all rectal transections were successfully completed with two firings of a 45-mm robotic stapler. When a circular stapler is used to perform colorectal anastomosis, the lateral areas of the transverse staple line, commonly referred to as “dog ears”, could be a potential site for postoperative anastomotic leak due to tissue ischemia. We have demonstrated in our study participants that application of the KHANS technique enabled these weak areas to be reinforced by interrupted sutures.

As part of the assessment of the anastomosis, ICG provides an evaluation of the vascularity of the proximal and distal intestinal segments. [19-21] The current evidence for its routine use is still limited;[19,21] a retrospective review by Jafari et al. [20] demonstrated a change in plans in 20% of cases after ICG injection. However PILLAR IIIL trial results , reported no difference in anastomotic leak between perfusion and standard groups. [21]

Blood loss in our patient group was minimal (10 ml) as compared to some published series **[22]** and reflects the precision and accuracy of this surgical approach. We believe that precision surgery with minimal collateral damage can result in better healing and prevent the need for a diverting stoma or the delay in stoma reversal. The length of hospital stay and readmission rates are also directly linked to the temporary stoma formation. The readmission rate in our study was low (4%) compared to the published figures of 10-15% **[23]** which we believe to be the result of lower complications combined with avoidance of stoma-related morbidity. The detailed assessment of vascularity and perfusion and accurate placement of a stapler to divide the rectum, followed by suture reinforcement of the colorectal anastomosis to cover the ends of the linear staple line and enhance the strength of the colorectal anastomosis, can all lead to a low incidence of anastomotic leak and obviate the need for a temporary diversion. We have successfully employed this technique in 50 patients (**Table 1**), all of whom had TME surgery without a defunctioning stoma. Suturing deep in the pelvis is a challenging

task and carries a significantly steep learning curve. EndoWrist instruments and 3D vision simplify this complexity, and even junior surgeons are able to accomplish this with minimal training. The median operating time in our series was acceptable (230 min) compared to the recently published ROLARR trial (298 minutes) and a series from MD Anderson Cancer center **[24,25].**

While 75% of the anastomoses in our series were below the peritoneal reflection, and one patient had radiological anastomotic leak managed conservatively with antibiotics and serial imaging, use of the KHANS technique in our group demonstrated positive results and enhanced patient outcomes compared to the literature, which reports an incidence of anastomotic leak of 8-10% after TME surgery [14,15]. If the anastomotic leak rates in a unit are low, creation of diverting stoma after TME should be highly selective. This technique canoffer surgeons the confidence of ensuring a good blood supply, adequate transection, and a healthy and secure anastomosis, thus reducing the risk of a temporary diversion.

One of the limitations of our study is **low anastomotic leak rate of 2-4%. It is the question whether this can be attributed to the KHANS protocol. To address this one would need to compare this group to a group of patients that was operated when the KHANS technique was not yet applied. However the higher rates of diverting ileostomy in the patients where KHANS technique was not used makes this comparison difficult. A prospective randomised trial to compare low anastomosis without diversion with or without KHANS technique would be the best way forward to evaluate this technique further**

Moreover, we enrolled patients selectively. We considered patients with poor functional and nutritional status, immunosuppression, and poor response to chemoradiotherapy as high risk for anastomotic leak, and this technique was not employed in such patients. However with increasing surgeon experience, such patients may also benefit from this technique. Furthermore, this is a retrospective review of consecutive cases and a single institution series. A prospective, randomized trial of mid to low rectal tumorswith or without diversion (using suture reinforcement) will provide a better understanding of the applicability and usefulness of this approach.

Conclusion

The KHANS technique (Key enHancement of the Anastomosis for No Stoma) can be successfully and safely employed using a robotic platform to assess the perfusion of the anastomosis and secure the anastomosis safely using robotic suturing with an absorbable suture. The use of flexible sigmoidoscopy, as described in the triple assessment Portsmouth protocol technique, is also a valuable adjunct. This approach can help surgeons to reduce the risk of anastomotic leak and the need for a temporary stoma in this patient demographic.

Acknowledgements

Editorial support was provided by Deborah Nock (Medical WriteAway, Norwich, UK).

Declarations

Funding. None

Conflicts of interest/competing interests. The authors have no conflict of interest or financial ties to disclose apart from JSK who is a proctor and trainer with Intuitive surgical.

Ethics approval. The project was registered with the R&D department Portsmouth Hospitals NSH Trust.

C**onsent to participate.** All patients in this study provided written consent to treatment and data capture and publication.

Availability of data and material. The data is available on Portsmouth colorectal cancer database.

Authors' contributions.

Concept – JK

Materials – SS, IM

Data collection &/or processing – AW, NS, AA,

Analysis and/ or interpretation – AW, SN, JK

Literature search – NS, SS, IM, SN

Writing – AW, AA, JK

Critical review – AW, SS, IM, NS, MH, SN, NS, JK

Provenance and peer review

Not commissioned, externally peer-reviewed

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Table

Table 1. Outcomes of total mesorectal excision surgery using the da Vinci robotic platform, without the need for a diverting stoma in rectal resections (KHANS technique)

Patient characteristics (n=50)	
Gender, n (%)	
Male	32 (64)
Female	18 (36)
Age, median (range) (years)	65 (27-91)
Body mass index, median (range) (kg/m^2)	27 (20-46)
ASA status, n (%)	
I	7 (14)
II	38 (76)
III	5 (10)
Previous abdominal surgery, n (%)	
Yes	12 (24)
No	38 (76)
Operating outcomes	
Blood loss, median (ml) (range)	10 (0-50)
Operating times, median (range) (minutes)	
Robotic docking time	5 (4-20)
Robotic operating time	200 (130-360)
Total operating time	230 (130-360)
Conversion	0
Number of stapler firings, median (range)	2 (2)
Level of anastomosis (distance from anal verge), n (%)	
Low rectum (1-5 cm)	28 (56)
Middle rectum (5-10 cm)	22 (44)
Post-operative outcomes	
Length of hospital stay, median (range) (days)	5 (3-34)
30-day anastomotic leak (minor), n (%)	1 (2%)
30-day postoperative radiological pelvic collection, n (%)	1 (2%)
30-day re-admission, n (%)	2 (4%)
Pathological outcomes	
Lymph node harvest, median (range)	20 (7-47)
Distal resection margin, median (standard deviation) (cm)	4.00 (2-11)
Resection margin, n (%)	
R0	49 (98)
R1	1 (2)

Figure legends

Fig. 1 a) Robotic port placement for abdominal (left) and pelvic (right) dissection phases of surgery using the da Vinci Si system; b) robotic port placement for total mesorectal excision, using the da Vinci X system

Fig. 2 Indocyanine green immunofluorescence before transection of the rectal tube

Fig. 3 a) Stapler to divide the rectum, b) operative view

Fig. 4 a) Suture reinforcement of the transverse staple line, b) operative view

Fig. 5 Creation of stapled colorectal anastomosis. a) Protrusion of the spike of the circular stapler (Ethicon, CDH series) between the upper and lower half of the sutures; b) operative view, c) end-to-end colorectal anastomosis, d) suture reinforcement of the circular staple line anterolaterally between the 8 to 4 O'clock position

Fig. 6 Air leak and flexible sigmoidoscopy

Supplementary material

V1- Video demonstrating the KHANS technique in stepwise fashion

Figure 1a

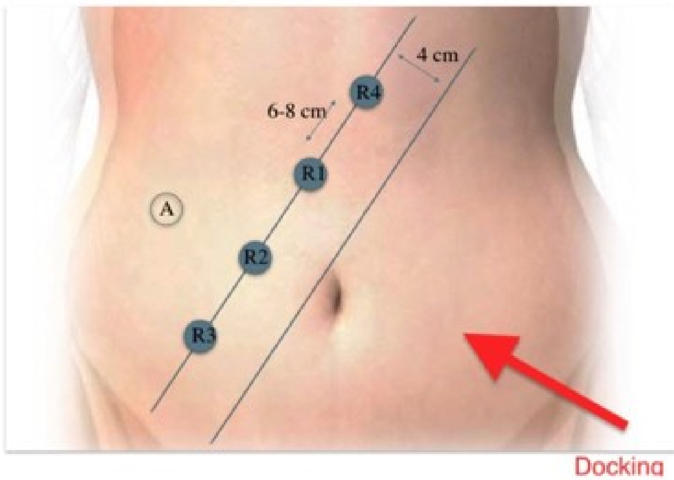
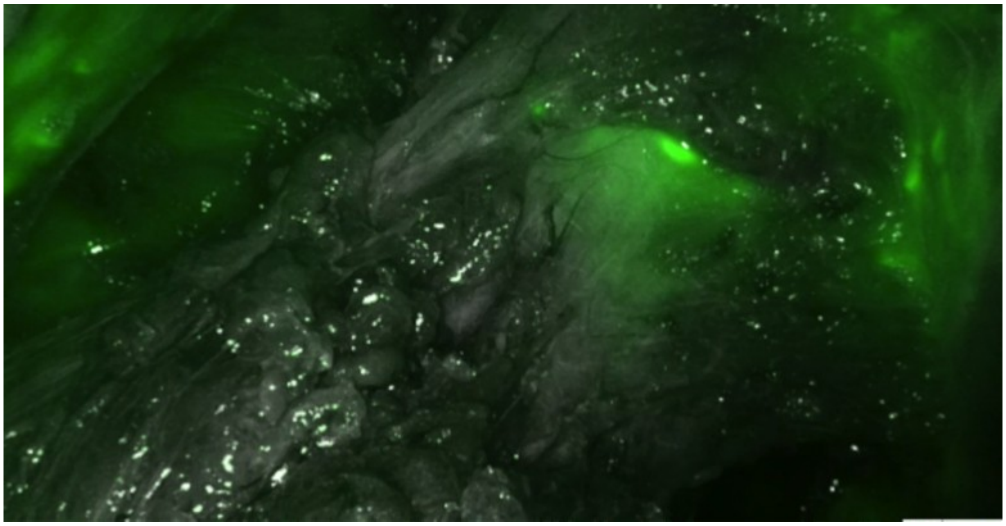


Figure 1b



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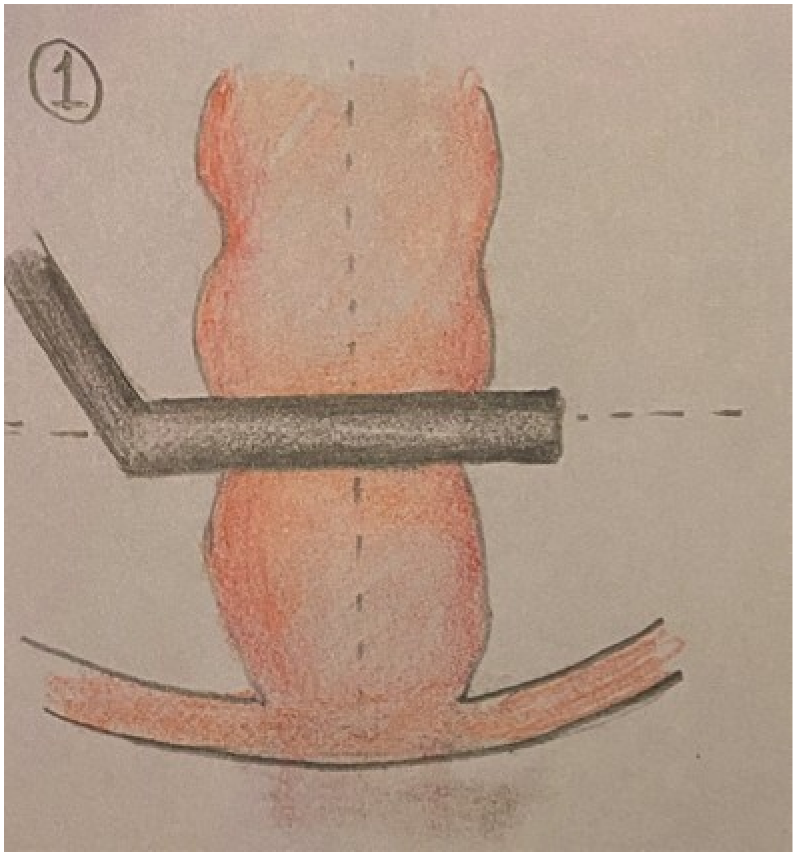
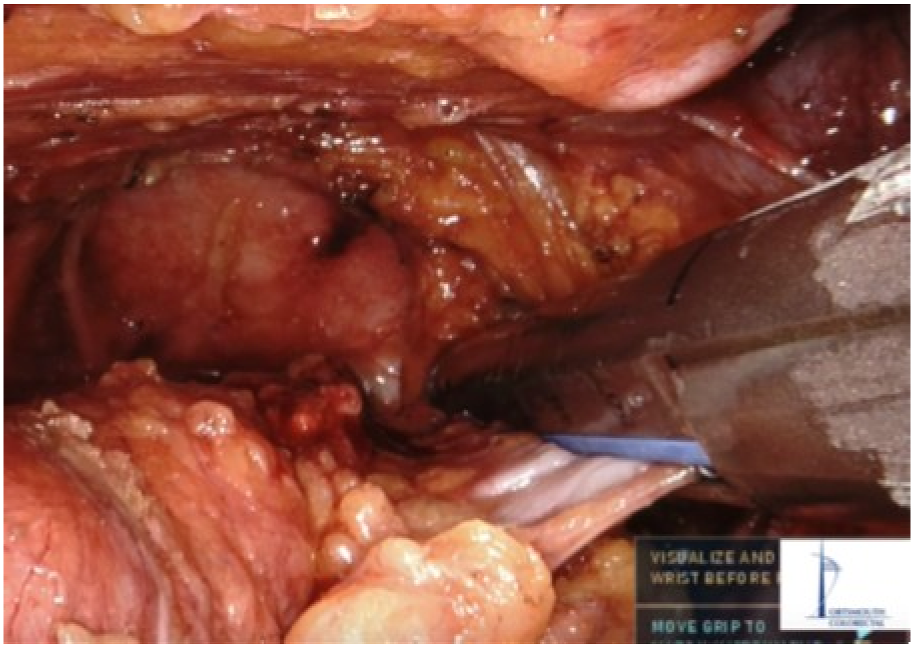


figure 3a



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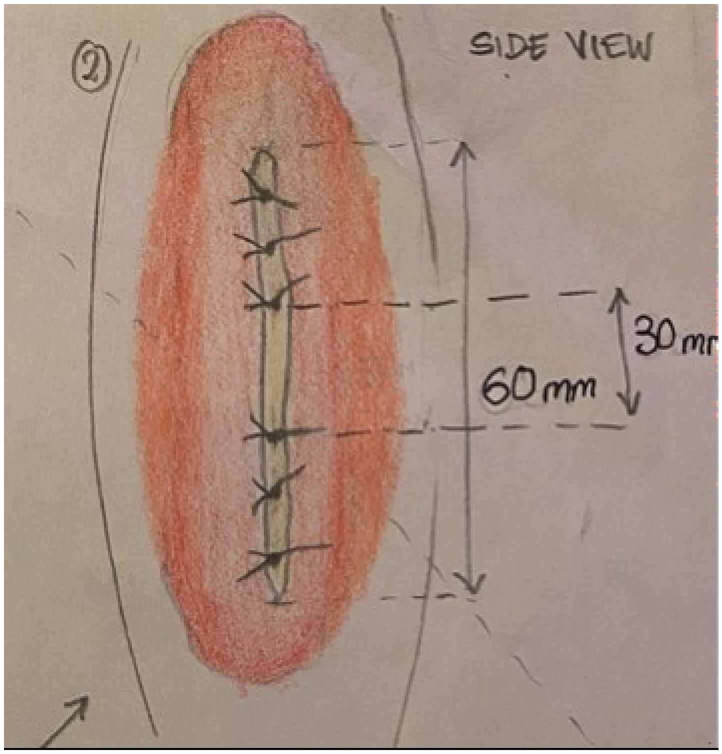

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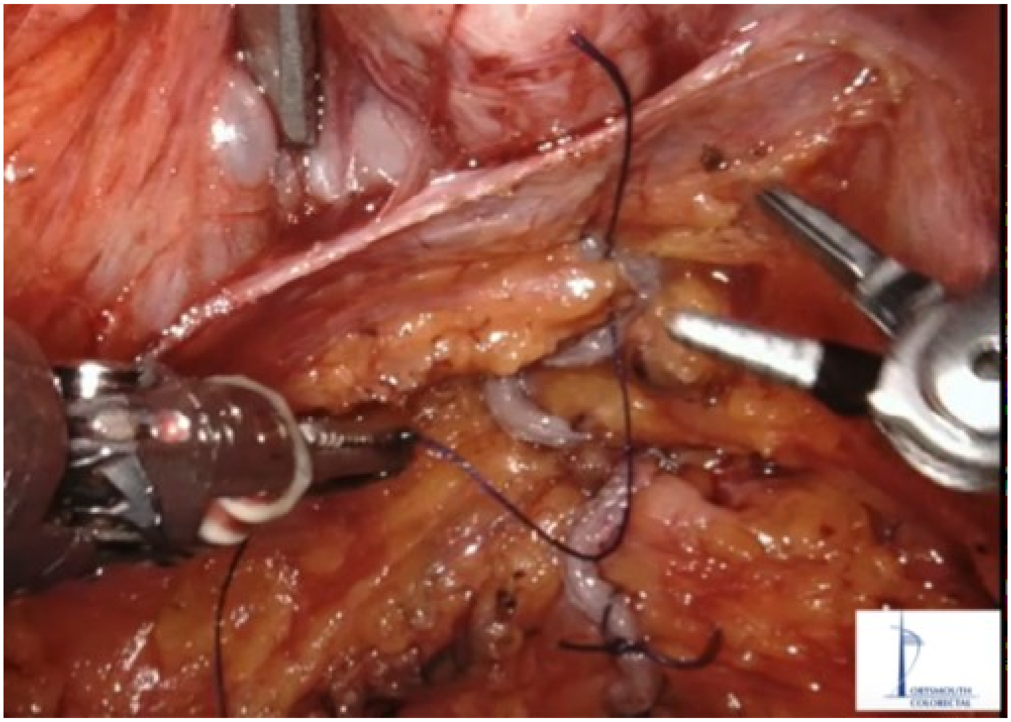

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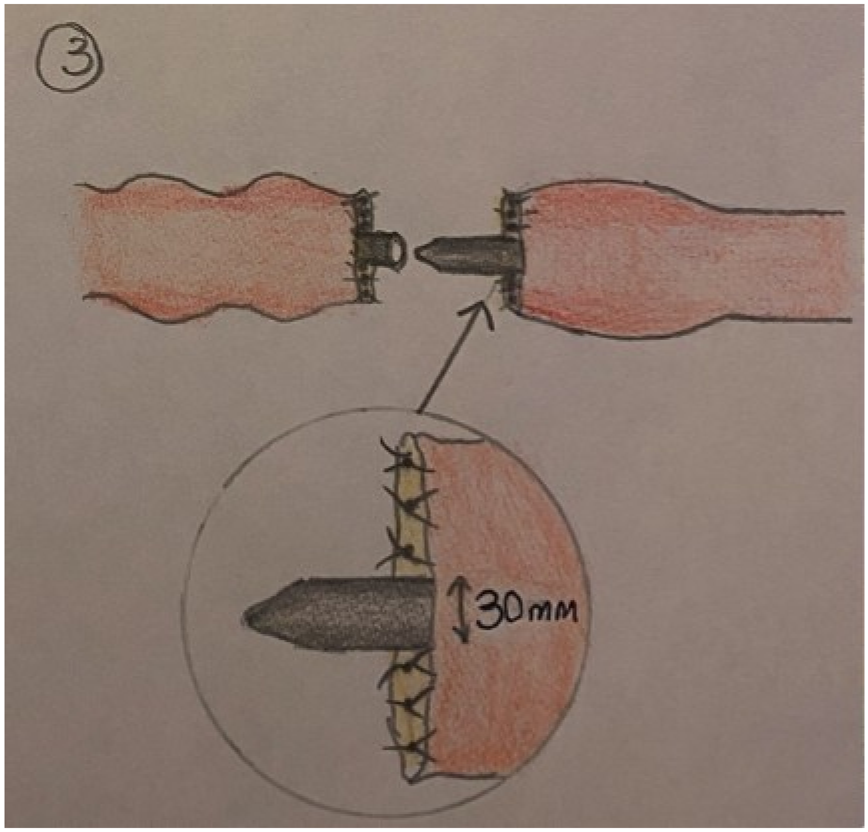

figure 5a

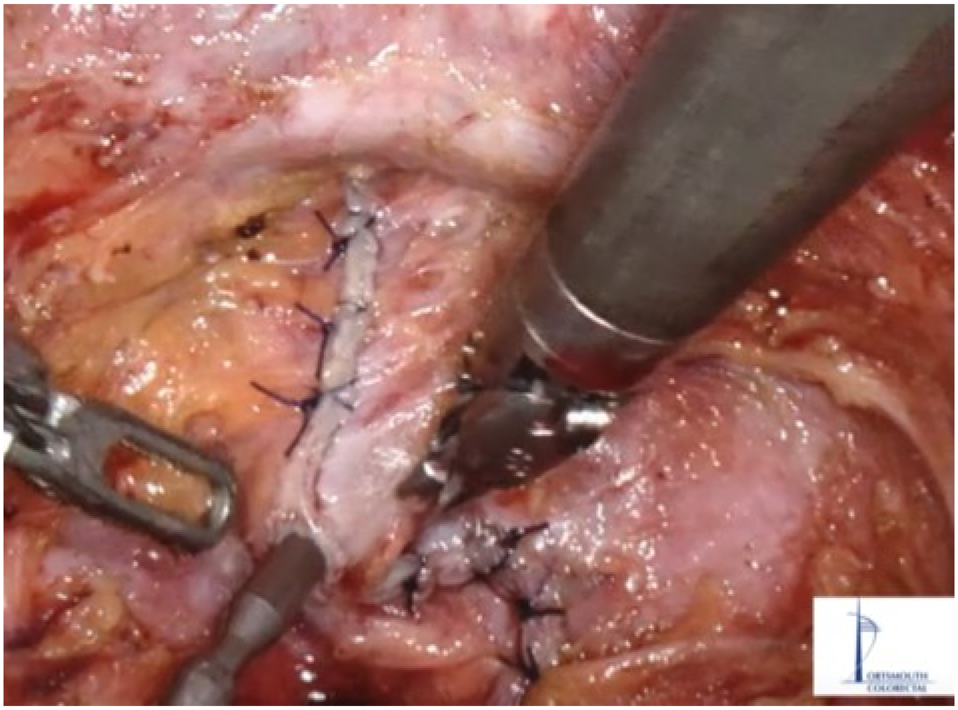

figure 5b

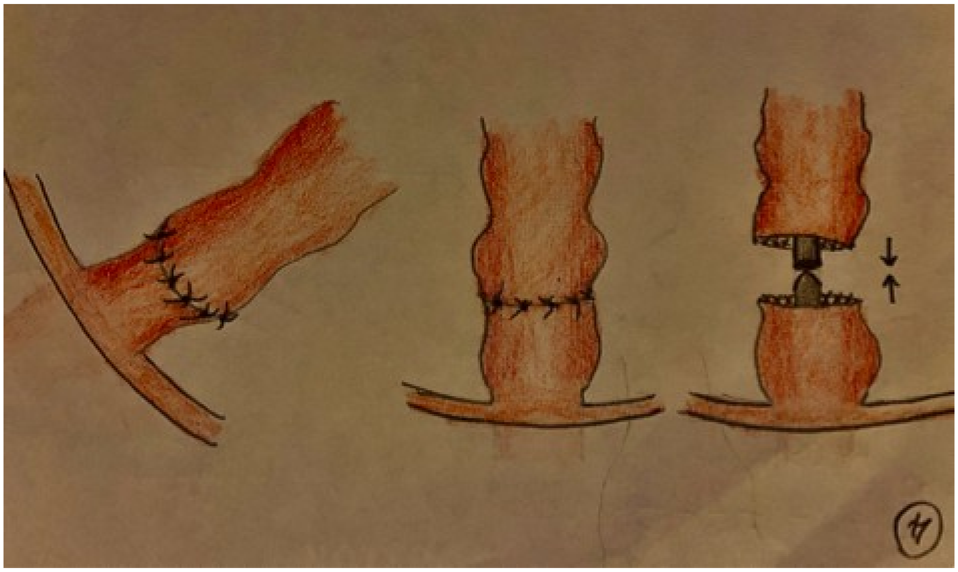

figure 5c

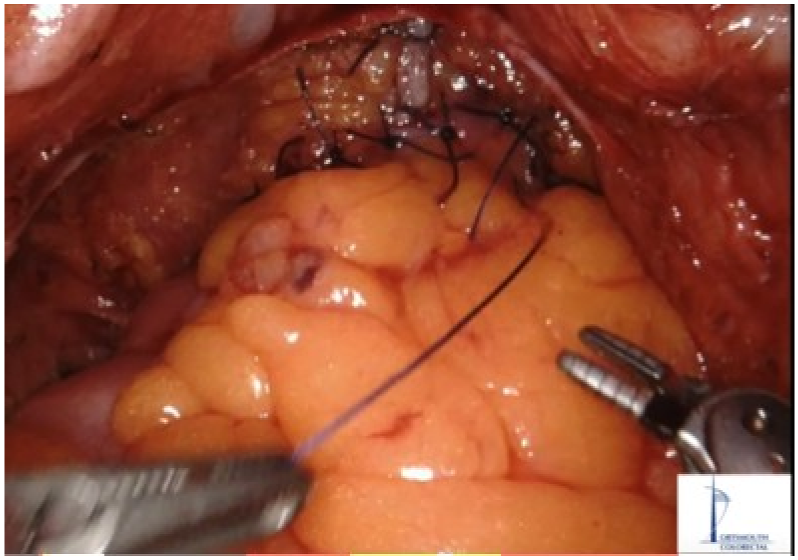

figure 5d

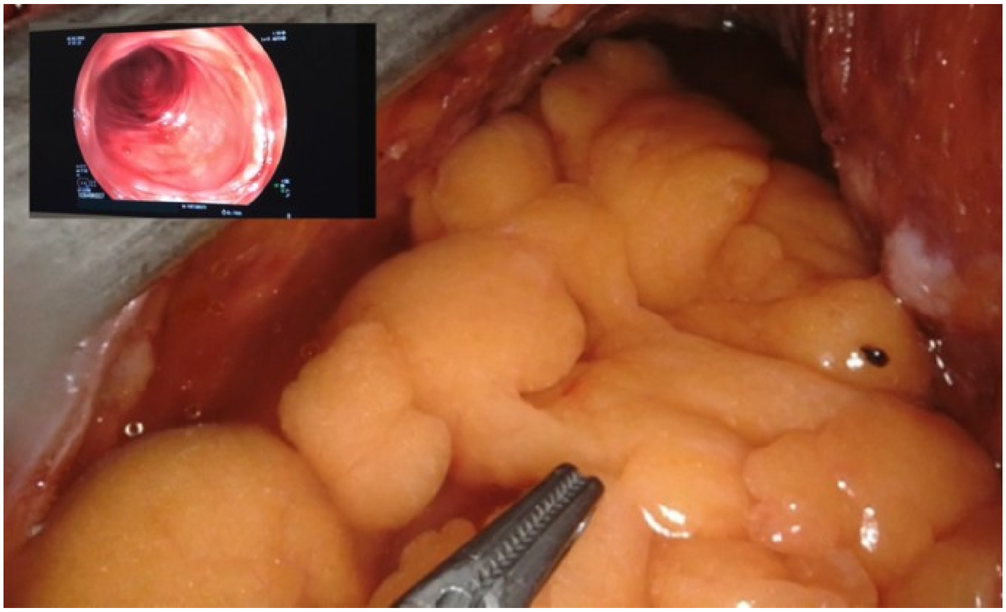

figure 6