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Development of a novel technique for transanal rectosigmoid resection and colo-rectal anastomosis

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1. Background

1.1. Transanal Endoscopic Microsurgery (TEM)

Transanal Endoscopic Microsurgery (TEM) is the first endoscopic operation performed in the area of visceral surgery and the development of the TEM technology was started in 1980 (19). TEM follows the principles of single port surgery, which means that optic and instruments are introduced in a parallel position. The TEM system comprises of a rigid rectoscope and the telescope and the hand instruments are positioned within it. The operative field i.e rectal lumen is distended with gas. The technology of TEM is highly sophisticated, and the hand instruments are specifically designed for the intralumenal work. The features of the TEM technology and that of the instruments are described below.

1.1.1. TEM technology and instruments

1.1.1.1. The rectoscope

The operating rectoscope is 4 cm in diameter and is available in two lengths, 12 and 20cm. It provides good accessibility throughout the rectum. The shaft of the scope is marked in centimeters to allow the surgeon to identify the level of insertion. The rectoscope is introduced into the rectum using an obturator and after the optimal position is defined, it is fixed using the articulating arm, a double ball joint support instrument. The working faceplate has a port for the optics and a snap-on multiport piece. The snap-on multiport piece contains three ports for long operating instruments. These ports are covered with airtight caps to maintain the pneumorectum. (Figure 1 and Figure 2)

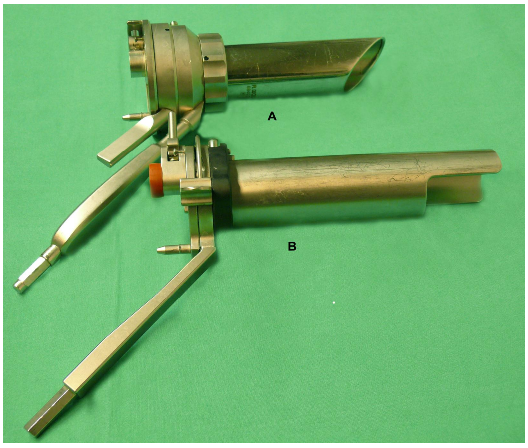


Figure 1. TEM rectoscope, the standard tube (A) and the window tube (B)

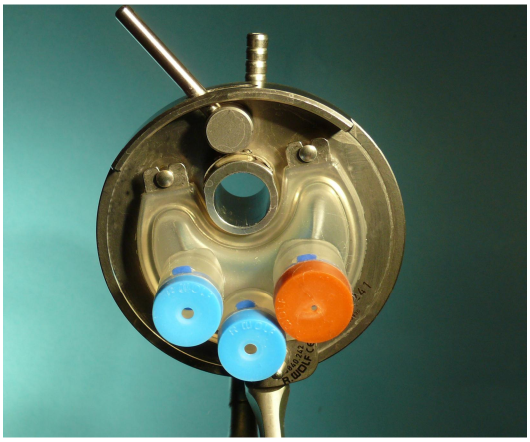


Figure 2. The face plate of TEM

1.1.1.2. The rectoscope

The surgeon uses a 13.8 mm binocular optic (stereoscope) which provides a high quality, three dimensional view. The optic is angled at the tip and at the eyepiece so that the surgical working field lies in front and beneath the tip of the optic. The surgeon has a direct stereoscopic view with upto six fold magnifications. The video camera is attached to the teaching optic inserted within the stereoscope and the operation can also be followed on the video monitor. Constant optimal exposure of the operative field is provided by automatic pressure- controlled gas insufflations. Carbon dioxide gas is used at a constant pressure of about 15 mm Hg. The suction, evacuation and the water rinsing are carried out by a roller pump system. (Figure 3)

Figure 3. The TEM optic, older version (Top), newer version (Bottom)

1.1.1.3. Surgical instruments

All the instruments are usually designed specifically for intralumenal work. Scissors and forceps are angled to the right or to the left. The forceps, needle holder, and suction device are bent to allow easy access to the rectal cavity. The suction canula is a long, double curved, rigid tube that is designed to be inserted through the rectoscope and stays at the side of the scope away from

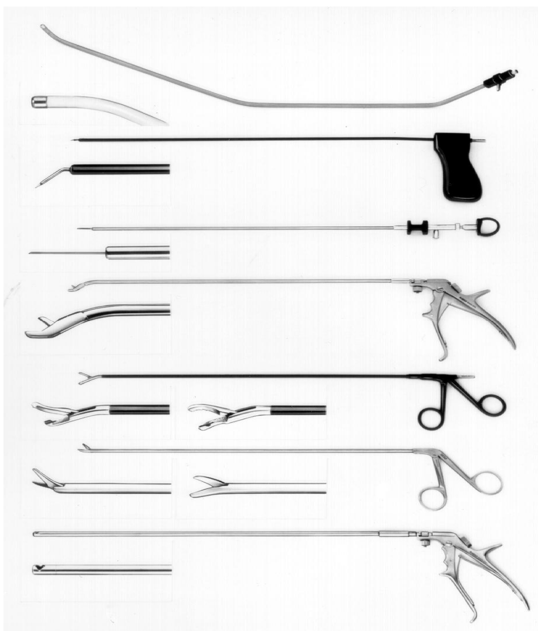


Figure 4. The instruments of TEM

the center or the operating field. Except in the tip, the shaft of the suction canula is insulated, thus blood can be suctioned while coagulating the bleeding vessel. The needle holders are available with either a straight or an angled tip. The angled tip provides a wider arc when the surgeon is passing a needle. The jaws are self righting, so when the needle is grasped it will rotate into the proper orientation. The needle can be locked in position with a rotating ratchet controlled by the surgeon's thumb. A clip applicator is used to press a silver clip on the suture as a substitute for the surgical knot. Clips are placed at the beginning and at the end of running suture. The thread used is commonly monofilament and reabsorvable. (Figure 4)

1.1.1.4. Articulated stabilizing arm

The articulating arm is attached to the operating table and serves as brace to hold the operating rectoscope firmly in place. There are two ball joints which fully articulate and are locked firmly in place with a single set screw. One end of the articulated arm is attached to the rail of the operating table using a specific insulated operating table clamp. The other end of the arm is attached to the operating rectoscope. The arm permits secure and steady position of the rectoscope without interfering the surgeon's ability to manipulate the instruments. (Figure 5)

Figure 5. The articulating arm holding the rectoscope

These specific technologies of TEM i.e. stereoscopic magnified view, dedicated angled instruments, controlled gas dilated rectum, etc. make it highly sophisticated technology and enable surgeons to perform a safe and precise resection of the rectal tumour.

1.1.2. Technique of TEM

1.1.2.1. Position of the patient

To facilitate excision of rectal tumours by TEM, the patient is positioned in such a way that the tumour occupies the bottom of the operative field. Accordingly, patients are positioned in dorsosacral position for tumours located on posterior rectal wall, side position for lateral tumours and abdominal position for anterior tumours. (Figure 6, 7,8).

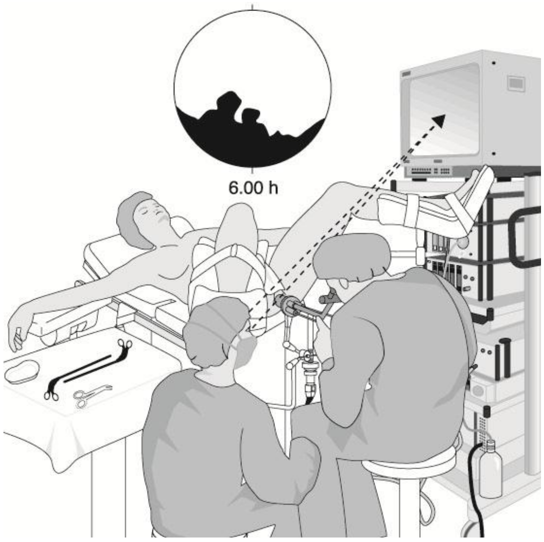


Figure 6. Patient position for the tumours located on anterior rectal wall

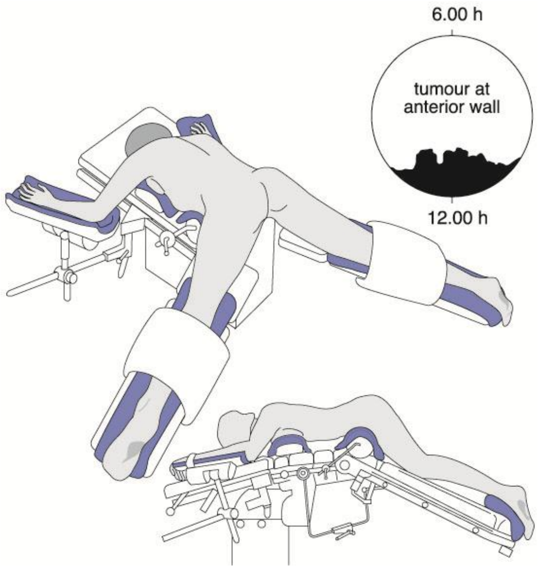


Figure 7. Patient position for the tumours located on posterior rectal wall

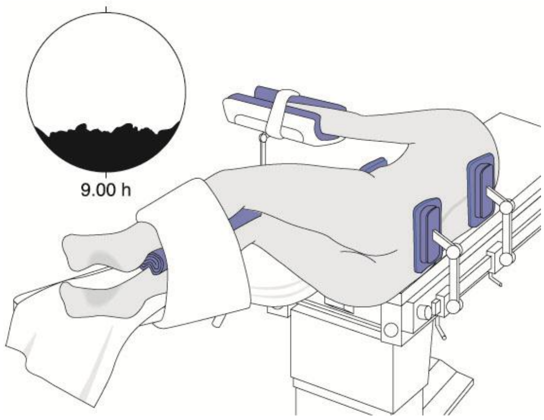


Figure 8. Patient position for tumours located on lateral rectal wall

1.1.2.1. Safety margin and division of rectal wall

After the rectoscope is inserted and its position is adjusted accordingly so that the tumour is placed at optimal locations, the coagulation points with high frequency or combination instrument are placed at a distance of 5-10 mm from the visible edge of the tumour. (Figure 9). The first cut on the rectal wall is made between the two coagulation points by high frequency or combination instrument and continued cranially and then in all directions. (Figure 10)

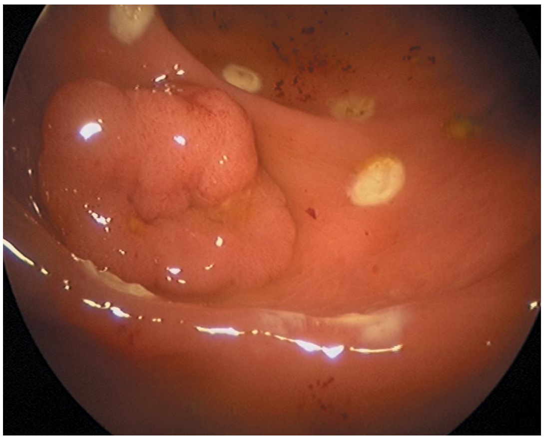


Figure 9. Coagulation points at 1cm safety margin

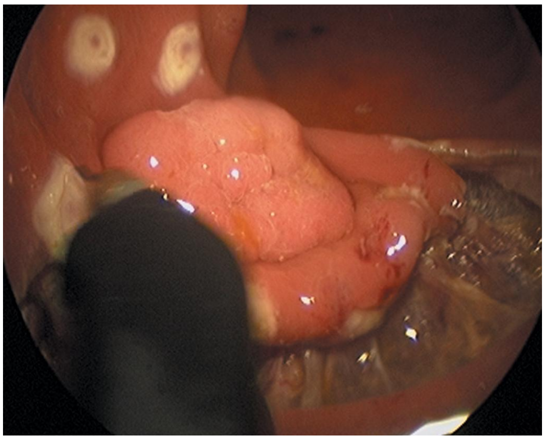


Figure 10. Dissection along the rectal wall

1.1.2.3. Excision of the tumour

The tumour is excised by full thickness excision or occasionally by mucosectomy. The perirectal fat is clearly identified beneath the rectal muscle and divided with high frequency or with harmonic scalpel. The tumour is then removed in toto without grasping the tumour itself. (Figure 11)

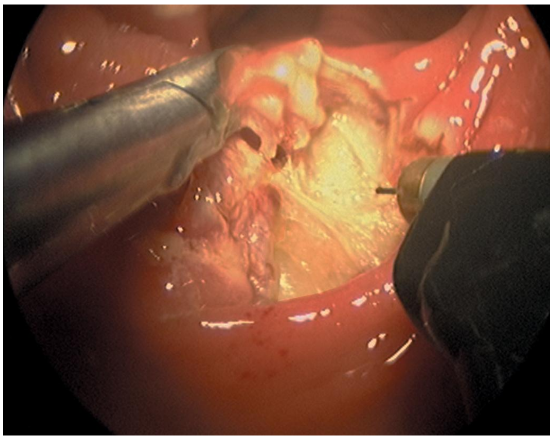


Figure 11. Full thickness excision of the tumour

1.1.2.4. Closure of the defect

Full thickness excision of the tumour leaves a semicircular defect on the rectum. (Figure 12A). The defect is closed transversely with continuous sutures starting from the right hand corner.(Figure 12 B). In case, the defect is very large, a stay suture is placed at the middle of the defect. Silver clips are placed on the suture at the beginning and at the end of suturing (Figure 12C, D). In case of inadvertent opening of the peritoneal cavity, the opening is closed with a separate suture.

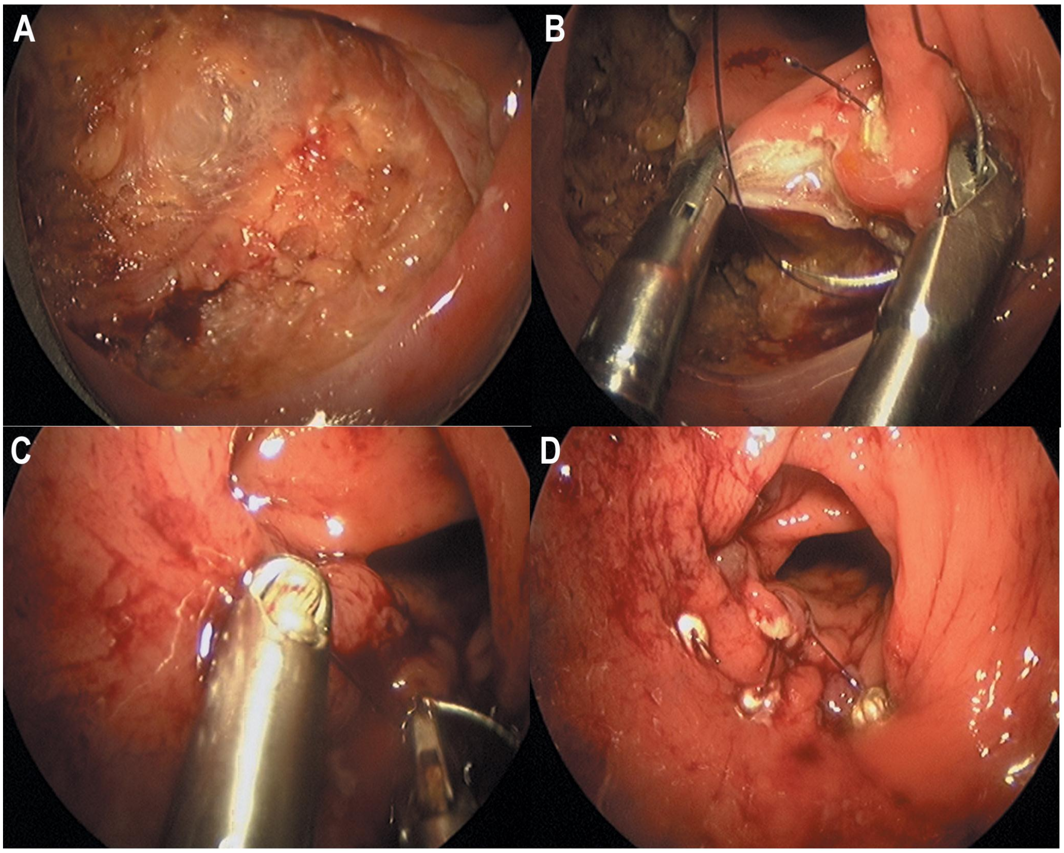


Figure 12. The defect after excision of a tumour (A) is closed by transverse suture (B). Silver clips are applied on the thread (C). Rectal lumen after repair (D)

1.1.3. Results following Transanal Endoscopic Microsurgery (TEM)

The first clinical result of TEM for benign rectal lesions was published in English by Buess et al. in 1985. This was a report of 14 cases on extra peritoneal part of the rectum. The tumours were excised completely either by submucosal resection or by complete full thickness excision without any post operative complications (20). The same group later published a large series of 140 cases of local excision of rectal tumours in 1988. These results were quite impressive and far superior to the existing result of local excisions by the conventional techniques (21).

Recently several large series have demonstrated the low morbidity and almost nil mortality following TEM for rectal adenoma and early rectal cancers. These authors agree that when applied to a selected group of low risk cancers, TEM has excellent oncological and functional outcome with low morbidity and almost nil mortality (3, 39, 84, 91). Although, initially TEM was applied on the extra peritoneal part of the rectum, with accumulating experiences, TEM seems to be feasible and safe for local tumours located on any part of the rectum and even for complex lesions (29,31).

The feasibility of local excision of rectal carcinoma by TEM lies in the fact that in the low risk pT1 tumours the possibility of lymph node metastasis is only 3% (43). Two multicenter trials also support that TEM can produce long-term outcomes similar to those published for radical total mesorectal excision surgery if applied to a select group of biologically favourable tumours (6, 8.). The comparative studies between TEM and radical resection for T1 rectal cancers reveal that TEM has significantly lower complication rate than radical surgical therapy and does not compromise the 5-year survival rate for low-risk T1 carcinomas (32, 41, 62, 82, 103).

The outcomes of TEM for selective low risk early cancers are impressive. However, the local excision of T2 tumour is associated with significantly high rate of recurrence specifically on high risk caners and not recommendable for routine practice (15). Attempts are made to downstage the tumours with pre operative high dose radiotherapy followed by local excision by TEM. The long term outcome of this approach is promising in selected uT2 and uT3 uN0 rectal cancers (64). However, more studies are required to confirm these findings.

1.1.4. Peritoneal breach in TEM

TEM was initially described for excision of adenoma on the extra-peritoneal part of the rectum. Full thickness excision in the intra peritoneal part of the rectum creates a defect communicating the rectal and the peritoneal cavity promoting a wide array of concerns of bacterial contamination of the sterile peritoneal cavity, safe closure of the defect to avoid subsequent peritonitis and the possible tumour cell implantation into the peritoneum. Thus, a peritoneal breach was long being considered as major complication of TEM mandating formal repair of the wound or an anterior resection by abdominal route. This perception limited the indication of TEM only to certain portion of the rectum (22). Also, in certain situation it may lead to a possible compromise in the resection margin in order to avoid the peritoneal breach (37). However, the expanding experiences on TEM and increased dexterity on intralumenal suturing has enabled surgeons a safe closure of such defects. Several authors have reported their experiences on intralumenal repair of the peritoneal breach.

dee Graaf et al. reported an incidence of 8.7% of peritoneal breach in their series of 353 consecutive rectal adenomas operated by TEM. However, this did not increase the operating time nor was associated with conversion. The morbidity or mortality of the patients was also not influenced by the peritoneal breach (31.)

The feasibility and safety of such repair has been extensively studied in two well known papers. Gavagn et al. in a single centre comparative study compared the outcome of TEM with and without the peritoneal breach. There were 11 patients with peritoneal breach while 23 patients had no peritoneal breach following TEM. The mean age, ASA classification, distance of lesion from the anal verge, and gender distribution were similar in both the groups. There was no difference in operative time, length of hospital stay, margins, and post-operative use of antibiotics. Ninety one percent of patients with entrance to the peritoneum left home within 24 hours of operation. All the peritoneal entries were repaired transanally via the endoscope and no one required laparotomy. No patient with peritoneal entry was treated for intra-abdominal sepsis or abscess and there was no significant difference in the incidence of either minor or major complications. The authors concluded that peritoneal breach during TEM operation does not increase the short term complication when the perforation is repaired primarily (37).

In a recent multi-centre trial by Butrap et al. there were twenty-two cases of peritoneal breach among the 888 TEM procedures performed for rectal cancers. All the perforations were closed primarily and no conversion to open surgery was made. Except one case of post-operative atrial fibrillation, there were no post-operative complication *nor any* procedure related mortality. During the mean observation time of 36 months, there were one local recurrence for pT1 cancers (7%) and another for pT2 tumours (25%). Distant metastasis occurred in three patients. Thus, peritoneal breach, although considered as one of the most feared technical complications of TEM, did not seem to increase the risk of short term complications or major oncological consequences like local recurrence or distant metastasis (7).

These detailed analyses emphasize the safety of full thickness resection of the tumour on the intraperitoneal part of the rectum, provided the defect is adequately repaired. In the context of NOTES, these evidences strongly support the feasibility of transrectal route for intra abdominal procedures. Safe viscerotomy closure is still not possible by flexible endoscope, and TEM with years of clinical experience can bridge the gap.

1.1.4. Effects on anal sphincter and quality of life following TEM

TEM essentially comprises of insertion of a 4cm diameter rectoscope through the anal sphincter. The patho-physiological consequences of this forceful dilatation of the sphincter and their impact on the quality of life have been investigated by several authors.

The anorectal function is impaired with significant sense of urgency following TEM. These impairments are more on elderly patients and in those with diminished continence pre-operatively. However, these changes are transient and improve significantly over one year time. The mechanical trauma to the anal sphincter also cause a transient decrease in anal squeeze pressure and a permanent decrease in resting pressure (9, 58).

A fall in resting pressure was correlated with length of surgery and procedures lasting longer than two hours may put patients at risk for internal sphincter damage, but without clinical relevance (54).

Evaluation of anorectal sphincter functions by endoanal ultrasound, anorectal manometry and rectal barostat revealed internal sphincter defect in 29 percent, moderate alterations in continence in 21 percent, and a permanent decrease in rectal wall compliance at six months following TEM. Pre-operative impairment in continence, the extent and type of excision were associated with significant impairment in postoperative anal function (42).

Recently, an elaborate evaluation of functional outcome following TEM has been published by Cataldo et al. They studied the number of bowel movements per 24 hours, ability to defer defecation, Fecal Incontinence Severity Index (FISI) and Fecal Incontinence Quality of Life (FIQL) before and 6 weeks after TEM. There was no difference in bowel movements per 24 hours and ability to defer defecation. There were no statistically significant changes in FISI and FIQL scores. They concluded that TEM has no adverse effects on ability to defer defecation, number of bowel movements per 24 hours, fecal incontinence, or quality of life (as related to fecal incontinence) (25).

Thus it can be concluded that anorectal function is well preserved in patients who have undergone TEM and any symptomatic or physiological impairment is usually transitory and resolves within 12 months. However, patients with pre-operative alterations in continence, particularly when longer operative time or large rectal resections are anticipated, are at risk of partial post-operative incontinence.

1.2. Laparoscopic colo-rectal surgery

The overwhelming benefits of laparoscopic cholecystectomy have motivated the surgeons to take up laparoscopic colorectal surgery. After the first description of laparoscopic colorectal resection by Jacob et al, there has been tremendous growth in this field (46). However, laparoscopic colorectal resection is technically demanding, has a steep learning curve and needs considerable expertise on laparoscopic surgery. Hence, it is still evolving.

1.2.1. Technical details

1.2.1.1. Patient positioning and the position of the trocars

The patient is positioned in a modified lithotomy position. The right arm is positioned alongside the patient and the left arm may be extended to facilitate vascular access for the anaesthesiologist. The abdomen, pubis, and perineum are prepared with providione iodine solution. The main video monitor is placed on the left side of the patient and the second at the left shoulder. There are several variations on the placement of trocars and position of the surgeon. The commonly used trocar positions are demonstrated in figure 13.

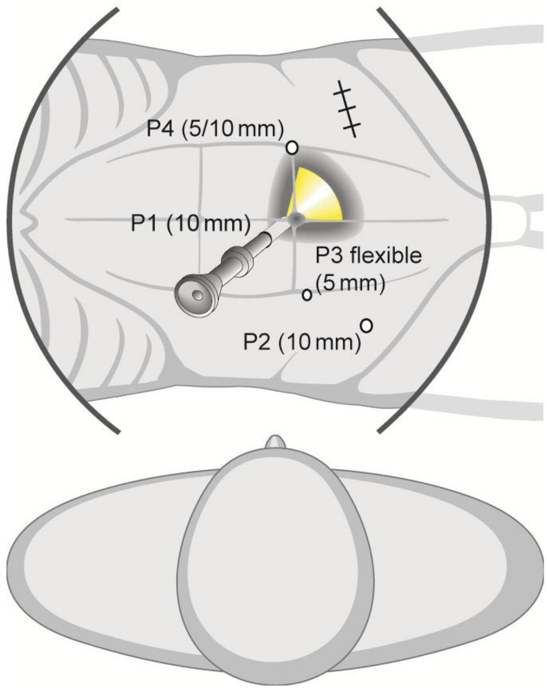


Figure 13. Position of the trocars

1.2.1.2. Exploration of the abdominal cavity

The entire abdominal cavity is systematically explored to rule out any pathological process that would preclude laparoscpic resection.

1.2.1.3. Mobilisation of descending colon, sigmoid colon and the splenic flexure

Mobilization of the colon is started by dividing the congenital peritoneal attachment of the sigmoid on the left iliac fossa and then proceeds cephalad along the left paracolic gutter till the splenic flexure (Figure 14, 15). The splenic flexure is made free according to the need of the procedure.

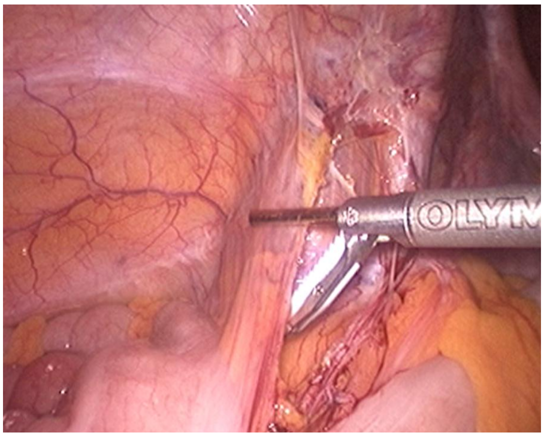


Figure 14. Mobilisation of the colon along the left paracolic gutter

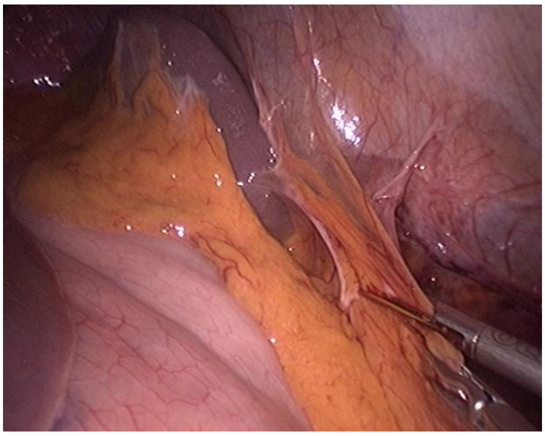


Figure 15. Mobilisation of the colon near the splenic flexure

1.2.1.4. Mobilisation of the rectum

The left ureter is identified and dissection is carried to pelvis to the left of the rectum safeguarding the left ureter. The peritoneal reflection of the Douglas space is sectioned in front of the rectum and Denonvilliers' fascia is opened. At the level of the promontorium, the presacral plane is opened and the rectum is mobilized with blunt dissection following the avascular plane, limited by the presacral fascia (Waldeyer's fascia) posteriorly and by the mesorectum anteriorly. (Figure 16) and a total mesorectal excision is performed with same standard as in open surgery.

Figure 16. Mobilisation of the rectum from the presacral fascia

The ultrasonic scissors are used to divide the adhesions between Waldeyer's fascia and perirectal fat upto the origin of the inferio mesenteric artery. Once identified, the artery is then divided after the application of endoclips or using a 35 mm vascular linear cutter (Figure 17,18).

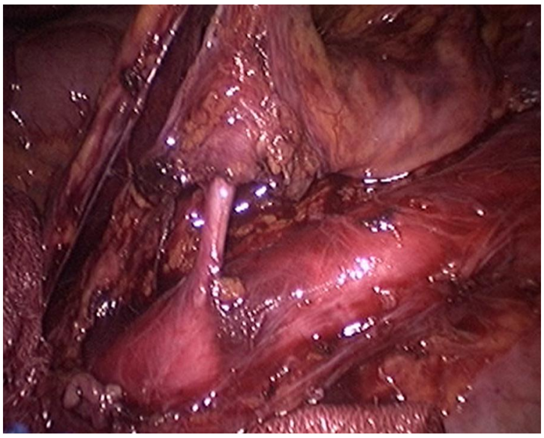


Figure 17. Inferior mesenteric artery prepared for clipping

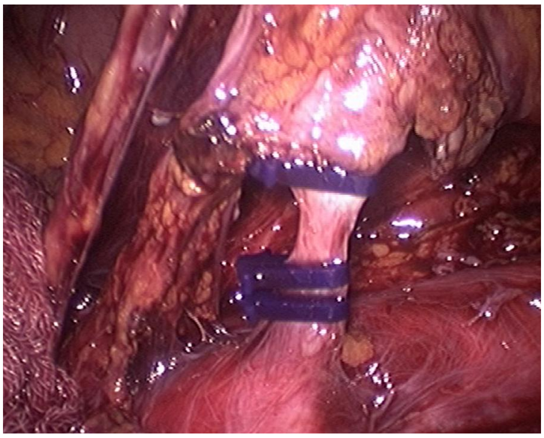


Figure 18. Inferior mesenteric artery is clipped with endoclips

The inferior mesenteric vein is also isolated and divided using either of the above mentioned methods.

At the limit set for the rectal transection, the mesorectum is dissected by electro-cautery or ultrasonic scissors until the muscular wall is freed on its entire circumference. The rectum is then transected by linear staplers with cutter. (Figure 19).

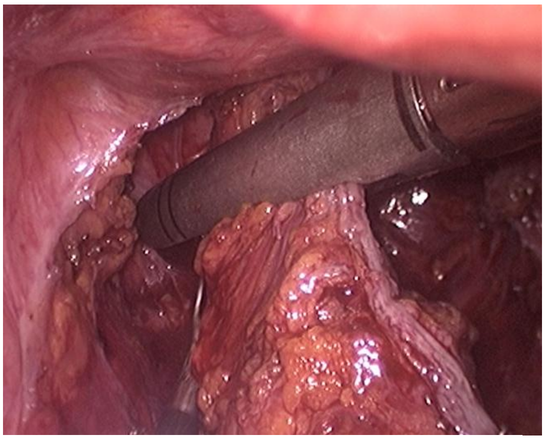


Figure 19. Transection of the rectum with linear stapler

1.2.1.5. Minilaparotomy to remove the resected specimen and to prepare for the anastomosis

A minilaparotomy of 5-8 cm is performed on the left lower abdomen. A plastic wound protecting drape is inserted. The colon is brought out through this and transected at a desired level. The anvil of the stapler is introduced into the proximal bowel and is secured by a purse string suture (Figure 20). The proximal colon is reintroduced to the abdomen with the anvil in situ and it is ready for the anastomosis. The minilaparotomy is closed in layers and abdomen is re-insufflated.

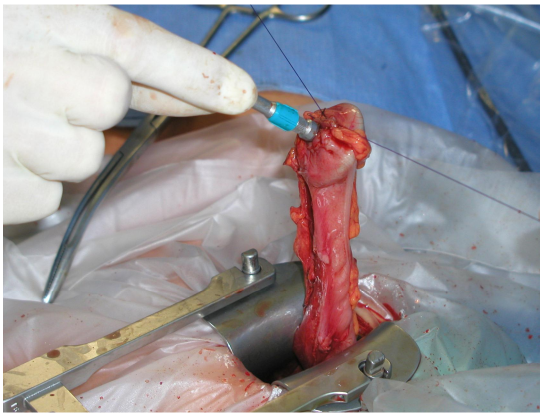


Figure 20. The stapler anvil is secured to the proximal colon

1.2.1.6. Laparoscopic colorectal anastomosis

The circular stapler is introduced through the anus and the trocar at its end perforates the stapled end of the rectal stump. The anvil, with the proximal colon is brought down to the rectal stump with the trocar of the circular stapler pointing out of it. The anvil and the trocar of the circular stapler are mated under laparoscopic assistance (Figure 21). The stapler is closed and fired to anastomose the colon and the rectum (Figure 22)

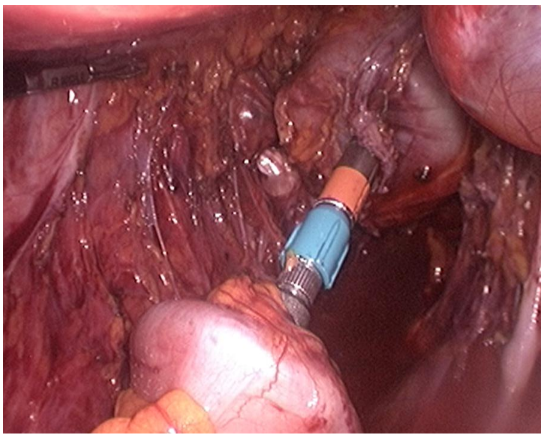


Figure 21. The anvil post and the stapler are mated under endoscopic vision

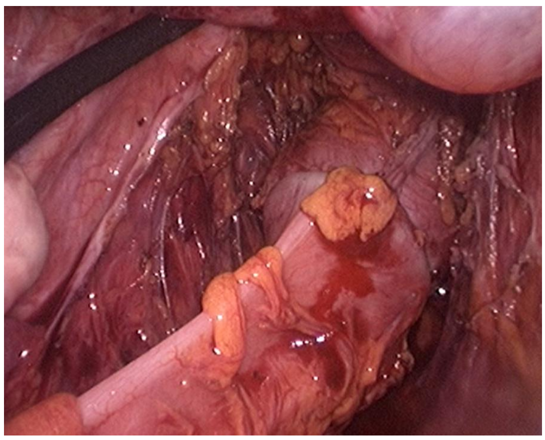


Figure 22. The stapled colorectal anastomosis

1.2.2. Specimen retrieval after laparoscopic colorectal surgery

The resected specimen after laparoscopic colorectal surgery is commonly removed by a minilaparotomy on the left lower abdomen. Although, the length of such minilaparotomy is very small but, it still has its associated morbidities. To avoid this minilaparotomy, several authors had explored other options like rectum and vagina as a portal for specimen removal. Presently, in the context of NOTES and single port surgery, these alternative options of specimen removal have regained interest.

Jackob et al., in the first series of laparoscopic colorectal resection, mentioned removal of the specimen via the transanal route (46). Darzi et al. described a totally laparoscopic way for sigmoid resection in 1994. They removed the resected specimen through the anus and inserted the anvil through the rectum. Although the technique looked appealing, it was technically demanding and hence was not popular (30). Breitenstein et al reported transvaginal delivery of sigmoid colon following simultaneous vaginal hysterectomy and sigmoidectomy (7).

In the context of NOTES and single port surgery, transanal and transvaginal specimen delivery has regained interest. Palanivelu et al. has coined the term “Natural Orifice Specimen Extraction, NOSE” for removal of specimen through a natural orifice. They performed laparoscopic total proctocolectomy in seven female patients and removed the specimen through the vagina (81).

Cheung et al. reported use of transanal endoscopic operation (TEO) device for transanal specimen removal in ten patients. None of their patients had any wound related problems and the recovery was fast (26). Similar totally laparoscopic sigmoid colectomy is also described by Akamatsu et al (2). Ooi et al described a slightly different technique. After removal of the specimen through the anus, they brought down the mobilized proximal colon outside the anus. The anvil of the circular stapler is then introduced in tothe exteriorized colon, secured by a purse string suture and repositioned into the pelvic cavity (79).

These authors were successful in removing the resected specimen either through the vagina or the rectum and thus avoided the minilaparotomy. Most of these reports were consistent, that by avoiding the minilaparotomy, the post-operative recovery could be hastened.

1.2.3. Anastomotic leakage following colorectal surgery

Anastomotic leakage is the most feared complication following colorectal resection and 2.8-30% of anastomoses eventually leaks. An anastomotic leakage significantly influences morbidity, mortality, prolongs hospital stay, increases local recurrence, worsens prognosis and raises the treatment cost (18,28,34,57,67,90).

The leakage rate for low recal surgery is higher than that of intraperitoneal part of rectum or other parts of colon. Various causes like patients' ASA score, rectal location of the tumour, surgeon's experience, transanal catheter placement, diabetes mellitus, prolong operative time, male gender, previous abdominal surgery, use of peri-operative steroids, contamination of the operative field, smoking, alcohol abuse are being implicated as risk factors. However, the type of operation (open or laparoscopic) and the technique of anastomosis (hand-sewn or stapled) are not crucial for anastomotic leak (94). Also, the single layer intestinal anastomosis has same leak rate as double layered anastomosis (88). In the context of laparosopcic surgery, certain factors like number of linear stapler firings used, size of circular stapler, crutch of linear staplers are also implicated as risk factors for anastomotic leak (44,55,60)

Development of staple technology has made colorectal anastomosis easier especially lower in the pelvis and due to the relative ease of using staplers; stapled anastomosis is the most preferred option for colorectal anastomosis. Meta analysis of randomized trials involving ileo colic anastomosis has shown superiority of stapled anastomosis over hand sewn in terms or anastomotic leak rate while other parameters were similar in both the groups (27). However, Cochrane meta analysis fails to demonstrate the superiority of staple anastomosis over hand sewn anastomosis for colorectal anasotmosis (68).

Although both the techniques yield similar results for colorectal anastomosis, the stapled anastomosis is more likely to be associated with intra-operative technical problems and post operative anastomotic strictures (69, 70). Thus, both techniques are effective, and the choice may be based on personal preference.

1.2.4. Outcome of laparoscopic colorectal surgery

Laparoscopic colorectal surgery was first performed in 1991, since then, it has gained steady momentum. Laparoscopy, by virtue of improved and magnified vision, less tissue trauma, better haemostasis has changed several aspects of colorectal surgery. In contrast to the 'touch guided' open approach, laparoscopy for rectal cancer offers a meticulous and easy dissection of the mesorectum under direct vision. Worldwide literature consistently demonstrates the short term benefits of laparoscopic colorectal surgery over open colorectal surgery. The patients following laparoscopic colorectal surgery have lower peri-operative mortality, lower wound complications, less blood loss, lower requirement of narcotic analgesia, passed flatus earlier, had bowel movement earlier, resumed diet sooner and were discharged earlier than the patients operated by open approach (77,78,96). In a meta-analysis of non-randomized comparative studies comprising 6438 resections for colorectal cancers, there was no difference in oncological clearance and of short term mortality between the laparoscopic or open resection. The laparoscopic group had early return of bowel functions, needed less analgesia, and had less short term morbidity; however, laparoscopic resection took longer time than open resection (1). Klarenbeek et al. in their prospective, multicenter, double-blind, parallel-arm, randomized controlled trial compared the outcome of laparoscopic and open sigmoid resection for symptomatic diverticular disease. They found significant reduction of major morbidities in laparoscopic group. Although there was no difference in minor morbidities, but the laparoscopic group had less pain, less analgesic requirement, returned home earlier and had better quality of life; however, the operative time was longer (56).

In spite of the favourable early outcome of laparoscopic colorectal surgery, the long term outcome in terms of oncological clearance, recurrence rate, port site or wound metastasis were concerns for long time. Recently several randomized trials have addressed these issues.

Meta-analysis of randomized control trial showed similar local recurrence, port site or wound recurrence, incisional hernia, reoperations for incisional hernia, reoperations for adhesions and cancer related mortality following laparoscopic or open resection for colorectal cancers; however, the assessments for rectal cancers were not conclusive (59). Another meta-analysis of randomized control trials has comprehensively evaluated the recurrence rate following open and laparoscopic colorectal surgery. There was no significant difference in local recurrence, overall recurrence, port site or wound recurrence and distance metastasis rate between the laparoscopic and open colorectal surgeries for cancer (65).

Meta analysis of four well designed randomized trials i.e the Barcelona, COST, COLOUR and CLASSIC trials have also demonstrated the oncological safety of laparoscopically assisted colectomy (14).Another systematic review of 10 randomised control trials involving 3830 patients found no difference in cancer-related deaths or recurrences between laparoscopic or open resection for colorectal cancers (45). The long term outcome of UK MRC CLASIC trial also suggest similar disease free survival, overall survival, local recurrence and quality of life after open or laparoscopic colorectal resection. Although, the rate of positive circumferential margin was more in laparoscopic anterior resection group, however, it did not influence the long term outcome (49).

Laparosocpic colorectal surgery, although, was slow to start with but gradually becomes a preferred mode of therapy worldwide. The safety and efficacy of laparoscopic colon surgery is beyond doubt, however, due to the technical demand, steep learning curve and the higher percentage of positive circumferential resection margin we need some more robust data to say the same for laparoscopic rectal surgery.

1.3. Natural Orifice Translumenal Endoscopic Surgery (NOTES)

The Natural Orifice Translumenal Endoscopic Surgery is a novel route to access the abdominal cavity. For centuries, the approach to the peritoneal cavity has been through an incision on the abdominal wall. Laparoscopic revolution of the late 20th century, although minimizes the degree of trauma to the abdominal wall, but an incision on the abdominal wall is still an integral part. The concept of transgastric approach to the peritoneal cavity with flexible endoscope, thereby completely avoiding the abdominal incision was pioneered by Kallo et al. They successfully performed transgastric peritoneoscopy and liver biopsy in a surviving porcine model and opened up a wide range of enthusiasm and research for scarless and painless surgery (50). Soon, the concept of transgastric peritoneal exoploration widened to involve formal transgastric intraperitoneal surgical task and surgical procedures like transgastric tubal ligation, gastrojejunostomy, gall bladder surgeries, ophorectomy, partial hysterectomy, splenectomy were shown feasible on the experimental set up (48, 51, 52, 72, 83,100). The other natural orifices like anus, urethra and vagina soon drew attention as a portal for entry into the peritoneal cavity and several studies had established their feasibility. (23, 66, 80).

The projected possible advantages of all these novel approaches to the peritoneal cavity are lack of surface incision, resulting in no scar on the abdominal wall, less pain during peri-operative period, less need for anaesthesia and analgesia and avoidance of abdominal wound related problems in the long run; also ability to perform procedures in patients where an abdominal incision is hazardous, such as in the morbidly obese patients.

Realizing the enormous potentials of these new access routes to the peritoneal cavity, there has been tremendous growth in research and development throughout the world. To control, guide and support these developments, under the auspices of American Society of Gastrointestinal Endoscopy (ASGE) and the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), a new working group was formulated as the Natural Orifice Surgery Consortium for Assessment and Research (NOSCAR) in New York City on July 22 and 23, 2005. This group defined these new developments as Natural Orifice Translumenal Endoscopic Surgery (NOTES) (85).

1.3.1. Limitations of flexible endoscopy for NOTES

The current endoscopes are designed for intralumenal work and are not optimal for intra peritoneal surgical task. Navigation to the target tissue is troublesome because simple push and torque techniques used in endoscopy, fail to propel the tip of the endoscope in a reliable manner. Orientation and re-orientation after disorientations is complex and difficult. Due to the lack of triangulation of the instruments at the tip of the endoscope, retraction and dissection of the target tissue is virtually impossible. In addition, the rotation of the camera view with rotation of the instrument disorients the operator and sometime moves the operating field out of view (89). Thus, most of the present clinical reports of NOTES like transvaginal cholecystectomy, appendectomy, trans gastric cholecystectomy, transvaginal sleeve resection of stomach, transvaginal repair of incisional hernia, transvaginal nephrectomy, transvaginal spleenectomy, transvaginal sigmoid resections are hybrid techniques combining the flexible endoscopy and the regular laparoscopic equipments. One or more transabdominal instruments are used for retraction, dissection, visualization, maintenance of pneumoperitoneum or combination of these (13, 35, 47, 53, 61, 71, 87, 95, 104, 105).

Another major obstacle for flexible endoscope is safe closure of viscerotomy. A safe and secure method for the closure of the viscerotomy is of paramount importance for the NOTES procedure and the progress of NOTES itself. There have been several innovative ideas and studies for safe viscerotomy closure. The different technologies presently employed for viscerotomy closure are clipping system like Jumbo endoclips and the Over-the-scope clips (OTSC, developed by our group), stitching system like T-Tag, LSI purse string suturing, NDO plicator, USGI G-Prox needle, Eagle Claw, and Flexible Endostitch, stapling system and occluding system like the Nitinol occluders. Each of these systems has its pros and cons. The staplers and occluders are effective but both lack security and staplers are difficult to use. None of the stitching technologies can be considered effective except for the Flexible Endostitch. On the other hand, flexible endostich is difficult to handle and not applicable to standard flexible endoscopy in the current fashion. Standard clips, although easy to handle but can not be considered reliable as only the mucosal layer closure has been demonstrated to date. The over-the-scope clip is likely to be effective, secure to introduce and simple to handle within the hollow organ (5). Thus a secure and safe viscerotomy closure by flexible endoscope is still investigational and there is need of much more technological development in this field.

1.3.2. Bowel anastomosis in the arena of NOTES

There is only limited literature focussing on bowel anastomosis with flexible endoscopy and mainly covers cholecystojejunostomy and gastrojejunostomy. This is due to the lack of dedicated suturing or tissue approximating systems in flexible endoscope. A prototype suturing device was used by Kantsevoy et al for creation of the gastrojejunostomy (51). An innovative technique was used by Bergström et al. for suturing the bowels. They used a 19 gauge Echotip needle loaded with a metal tag and attached to a polypropylene thread. The needle was advanced through the tissue under vision and the tag and thread was released from the needle and left in place. Pairs of such threads were placed on both stomach wall and small intestine and finally tied together to form the anastomosis (12). Animals in both these studies survived well. Park et al used both sutures and clips for cystogastrostomy with assistance of a transabdominal grasper (83). Mintz et al promoted dual-lumen NOTES approach; the resection and anastomosis were performed with regular laparoscopic staplers introduced through a port placed in the rectum (74). Fuchs et al reported use of flexible computer assisted stapling device for side-to-side small bowel anastomosis. However, the stapling device was introduced via an abdominal trocar and also sliding the bowel ends on the stapler branches were highly complicated (36).

Thus the experience of flexible endoscopy and bowel anastomosis is limited and needs much development in this area so that the established surgical principles of bowel anastomosis can be reproduced.

1.3.3. NOTES: Experiences in colo-rectal surgery

The feasibility of NOTES in pre-clinical and basic clinical settings has already been established. However, for the progress and expansion of this new domain, it is important to investigate the applicability of NOTES, not only in diagnostic or minor surgical interventions but also for major surgical procedures. The welcoming response for NOTES from surgeons as well as patients is a strong impetus for further development of techniques and technologies (92,98,99).

Whiteford et al. first investigated the feasibility of a more substantial operation like sigmoid colon resection through the natural orifice using the TEM system in human cadaver. They performed a circumferential mesorectal excision in a retrograde fashion, delivered the specimen through the anus and performed the colorectal anastomosis by circular stapler. The TEM system provided a good overview of the operating field and with proper bimanual activity. However, due to the short length of the TEM instruments, their cephalad extent of dissection was limited to the descending colon and they could reach only upto the proximal superior haemorrhoidal artery (102). The limitations, due to the short length of TEM instruments, were tried to overcome by the use of transgastric endoscopic assistance. The endoscopic assistance helped to resect longer specimen than the TEM system alone in porcine model (93).

Leroy et al described another technique of sigmoid resection using a double channel gastroscope in swine model. The dissections were performed with regular endoscopic instruments. They divide the colon by a linear stapler introduced to the peritoneal cavity through transrectally placed trocar. The specimen was delivered by a “pull through” technique through the anus. The anastomosis was made by circular stapler introduced through the anus. Manipulation of large organ like sigmoid colon with flexible endoscope is difficult. In this paper, they used a transanally placed rigid manipulator to retract the colon. This is possible only in animal model due to the midline and straight alignment of rectum and sigmoid colon. Feasibility of retracting sigmoid colon in human by a transanally placed rigid manipulator is questionable (63).

Lacy et al. reported the transvaginal resection of sigmoid colon in a 78 years old female patient with sigmoid adenocarcinoma. Most of the dissections were performed with minilaparoscopic instruments. A 12 mm transvaginal port was used for retraction of the colon and for the stapling of the vessels and the upper rectum. The specimen was removed through the vagina. The resected specimen was oncologically adequate. The patient had uneventful recovery and the benefits of minimal invasive surgery were enhanced. Although most of the dissections were performed with the mini-laparoscopic instruments, the report can be regarded as one step ahead for radical surgery being performed via natural orifices (61).

These reports of sigmoid resection either by transvaginal or transanal, clinical or pre-clinical, stressed on the need of robust instruments to manipulate large organs like sigmoid colon.

1.4. Experience of our group on research and technology

1.4.1. Tuebingen MIC Trainer

For reaearch and development of new technique and technology our group is using an innovative trainer, the Tuebingen MIC Trainer. The trainer has a unique shape resembling the human abdomen and is developed by our group in co operation with Richard Wolf GmbH (Knittlingen, Germany). It consists of four parts: fluid reservoir, dorsal abdominal form, abdominal wall and the neoprene cover. (Figure 23 and Figure 24).

Figure 23. The dorsal abdominal form of the Tuebingen MIC Trainer

Figure 24. The Tuebingen MIC Trainer with the cover on top

The fluid reservoir collects the organ fluid and also has a connection to the grounding electrocautery. The dorsal abdominal form is made of a metal net and is constructed exactly like the form of the human abdominal cavity. This part has an anus for the training of transanal endoscopic microsurgery, rectal resection and stapled anastomosis. The animal organs collected from the local sloughter house are reintegrated into it as in human anatomy.

The abdominal wall is a metallic wide mesh and the cover is made out of neoprene. The elasticity of neoprene is similar to that of human abdominal wall. So, it is possible to place multiple trocars with realistic resistance.

In our centre, the trainer has been used for training of basic and advanced laparoscopic procedures since 2005. The integration of animal organs into the human body form yields a more realistic anatomy compared to the training on the living animal. This is of specific importance in case of colorectal surgery due to the unique shape of the human pelvis, which is not seen in animal. The mesh structure of the trainer allows more precise anatomical positioning of the internal organs. Since the organs are real, the trainee can feel the forced feedback and dissection planes similar to those in human laparoscopic procedure (101).

1.4.2. Experience of our group on NOTES

1.4.2.1. Development of new instruments

The experimental works for Natural Orifice Translumenal Endoscopic Surgery (NOTES) was started in 2005 in the section of Minimally Invasive Surgery, Tuebingen University. TEM, by virtue of robust instruments, unique stereo-optic, and stable platform is a promising tool for NOTES. However, the TEM system was developed for intralumenal work, the instruments' length is not optimal for intra-peritoneal work, and hence further development is required. Initial task was to develop instruments dedicated for the translumenal intraperitoneal work. After a series of experiments and discussion with engineers and instruments developers, a new set of instruments were developed (Figure 25).

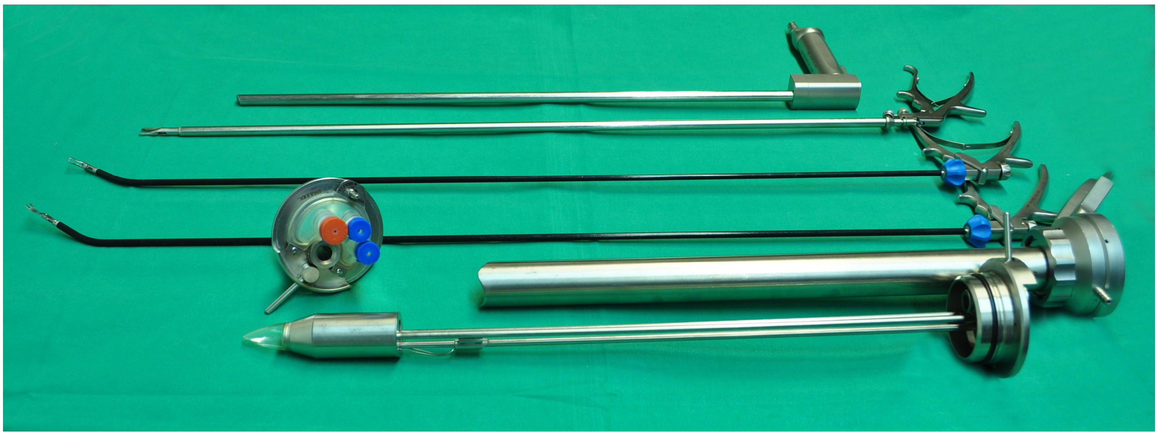


Figure 25. The new long instruments developed for transluminal intraperitoneal work

These instruments are based on the principles of Transanal Endoscopic Microsurgery (TEM) but are long, curved and steerable (24). In short, the system comprises of an optical trocar like TEM rectoscope but longer (60cm) and thinner (3.3cm) with a faceplate of TEM. The faceplate had four channels, three for working hand instruments and one for the optic (Figure 26). The hand instruments have a curved rotatable shaft and inside the shaft there are rotatable effectors like scissor or grasper (Figures 27, 28). Transmission of movement is controlled by thumb and index finger through two wheels close to the instrument handle.

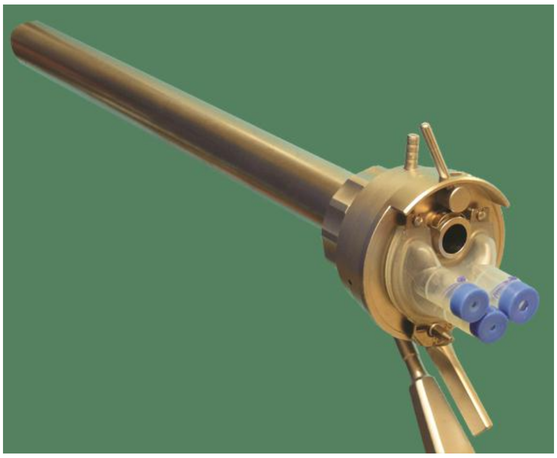


Figure 26. The long tube with the face plate of TEM

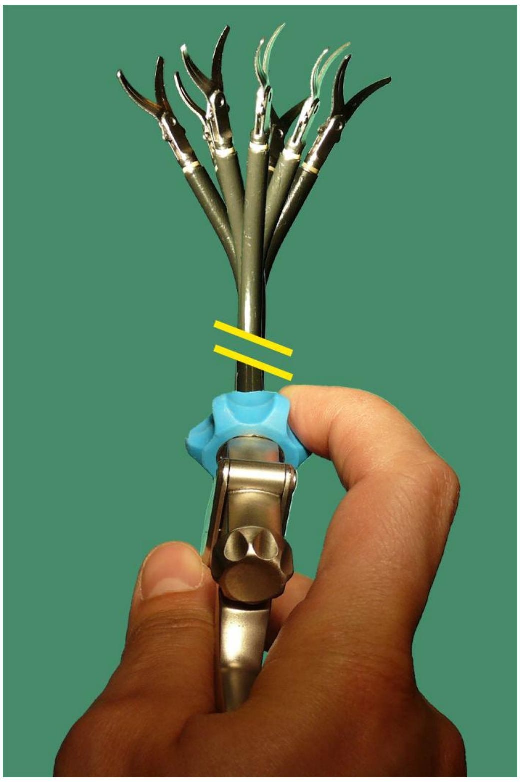


Figure 27. Rotation of the proximal wheel rotates the shaft of the instrument

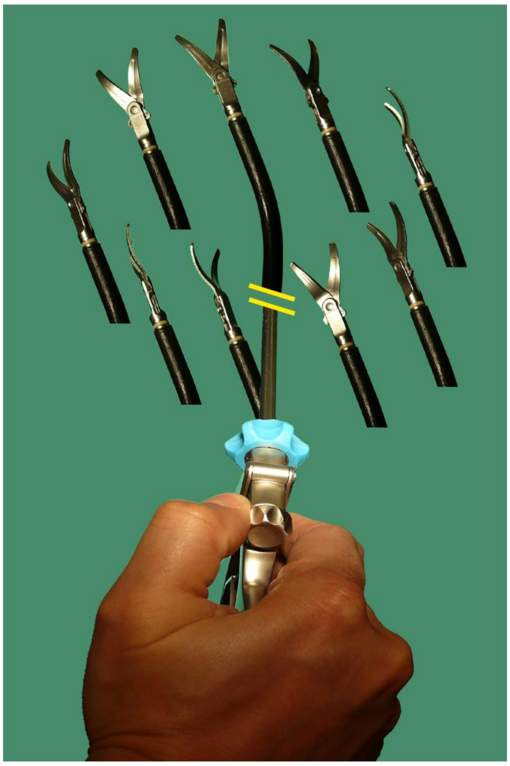


Figure 28. Rotation of the distal wheel rotates the effector

The optimal adjustment for a task can be reached intuitively with simultaneous movements of these wheels by the holding hand The specific curved designs of the instruments are important to reach a larger working field compared to straight instruments (Figure 29). Suction device and hook dissector for high frequency application are also developed.

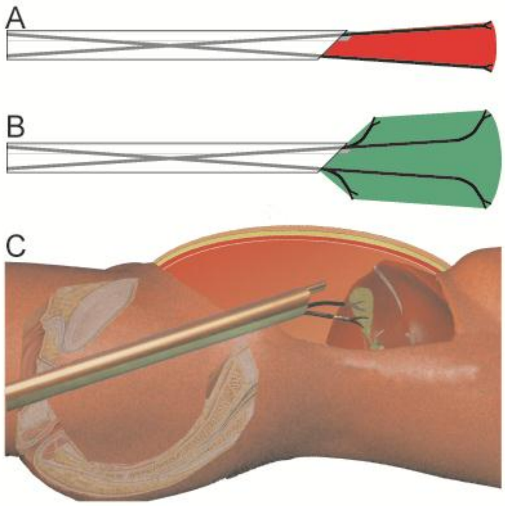


Figure 29. The curved design of the instruments helps to reach a larger working field

1.4.2.2. Experimental study on single port transvaginal cholecystectomy

After completing a phase of extensive work with in the prototype design, we set out to test the feasibility and the learning process for a new single-port-access transvaginal cholecystectomy (11). We designed an ex vivo experimental trial based on the Tuebingen Trainer (Richard Wolf GmbH, Knittlingen, Germany), which offers the possibility of simulating a transrectal–transvaginal approach due to its standardized human proportions and the built-in pelvic access of the design.

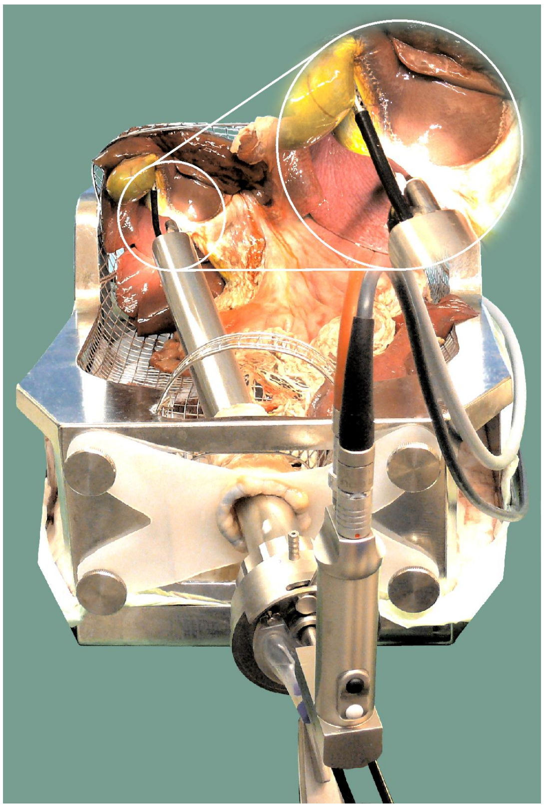


Figure 30. Experimental setup of transvaginal cholecystectomy

Porcine right liver lobes, complete with gallbladder and common bile duct, were obtained from the local slaughterhouse and either handled fresh or immediately deep frozen for later use. When frozen, they were thawed for 3 h before the procedure and then immediately used.

The organs were placed and fixed inside the trainer, replicating the normal human anatomy (Figure 30). Three surgeons with varying degrees of laparoscopic surgery experience participated in the study. Each performed 30 to 34 procedures assisted by either one or the other surgeon. Subject A had experience with75 to 100 laparoscopic cholecystectomies and a small number of more complex laparoscopic procedures at the beginning of the study. Subjects B and C both were professors in surgery with ample experience in complex laparoscopic procedures. All three performed transvaginal cholecystectomy through the single port access adhering to the established principal of laparoscopic cholecystectomy. Each procedure was video recorded for data analysis.

We then analyzed the technique/surgeon performance and instrument-handling performance. For analysis of tissue handling performance we evaluated the frequency of low grade and high grade injury to the liver and to the gall bladder. We also evaluated the conflicts between instruments and conflicts between the instruments and optics in three different grades i.e minor, major and severe conflicts to determine whether the instrument-handling characteristics had any influence on overall performance. The individual experience of each surgeon was divided into groups of 10 consecutive cases and the overall experience of the team was evaluated in groups of 15 consecutive procedures for analysis. Statistical analysis was performed using analysis of variance (ANOVA) with an alpha error of 0.05. Overviews of main results are presented on table 1.

Table 1.

Variables	Mean	Range	Standard deviation
Cholecystectomy time (min)	19.90	9.70-34.00	8.25
Calot’s triangle dissection time (min)	8.80	4.30-14.70	2.85
Liver bed dissection time(min)	11.20	3.75-18.60	4.39
Liver bed surface area (cm)	34.42	16,70-56.15	13.36
Performance errors-tissue	2.50	0-7	1.68
Performance error-instruments	5.25	1-11	3.06
No of instrument and optic position change	8.50	3-15	4.07

The individual time for each procedure and each surgeon is plotted with superimposing the corresponding logarithmic trend line on the following graph. For statistical analysis, we divided each of the surgeon's experiments into consecutive groups of 10 procedures (3 groups for each surgeon). In a comparison of the first and last groups of each subject, all the surgeons showed a reduction in both mean cholecystectomy time and mean errors but only one subject had a statistically significant reduction in time with ANOVA yielding F(1,18) = 25.25 (p\0.0001) (Figure 31).

The figure 32 represents the progressive reduction of errors (mean) with increasing group experience. The first group had 3.7 ± 1.65 errors, whereas the fifth group had 1.6 ± 1.04 errors (F[1,28] = 8.90; p\0.01), and sixth group had 1.9 ± 1.48 errors (F[1,28] = 7.12; p\0.05), both reaching statistical significance. This reduction in errors was dependent primarily on the reduction of high grade errors whereas the low-grade errors remained fairly constant.

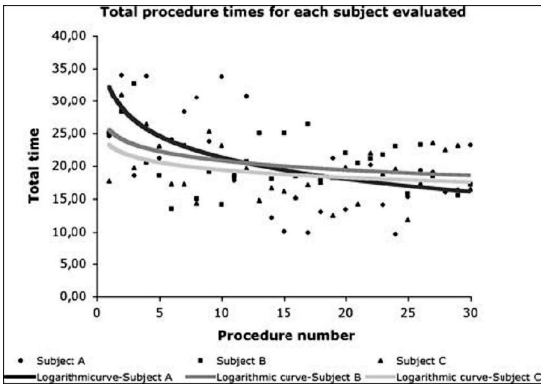


Figure 31. Reduction in mean operation time

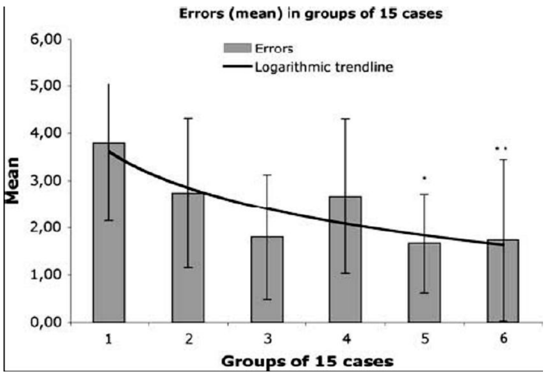


Figure 32. Reduction in mean errors

The Conflict between instruments and between instruments and the optic were not reduced with increasing experience but did not reach statistical significance (from 5.8 to 6.2). Although in the end they were not avoidable, when the reduction in time for the procedure is considered, it can be argued that they did not pose a significant obstacle.

From this study it was apparent that the tasks of cholecystectomy using the newly designed instruments can be learned safely in a reasonable number of simulations. A plateau seems to be reached after 15 cases, yet we cannot ascertain that this would be the case for every surgeon. Nonetheless, we consider that this brings us a step closer to a reasonable and safer introduction of the technique to clinical practice. Also, the analysis of the learning process as done in this study may help to reduce the preventable complications through the design of a comprehensive training curriculum.

1.4.2.3. Clinical study on transvaginal cholecystectomy

The ex-vivo analysis documented the feasibility and safety of transvaginal cholecystectomy in porcine model and as a next step to ward safe clinical application; we evaluated the feasibility of the technique in human cadaver. The results were quite satisfactory and paved the way for clinical application.

Six parous women with the history of symptomatic uncomplicated gall stone disease were selected. The patients and their husbands were explained about the possible advantages and complications of this new and largely investigational method. They opted for the new technique accepting the possibility of conversion to laparoscopy or to conventional open surgery Gynaecological examination was performed to exclude pelvic pathology. Abdominal ultrasonography was done for confirmation of the diagnosis.

All patients were operated under general anaesthesia. A single dose of a broad-spectrum antibiotic prophylaxis was administered one hour before surgery. The urinary bladder was catheterized with Foley’s catheter and the patients were placed in modified Lloyd Davis position.

Abdomen, pelvis and vagina were cleaned with 10% povidone iodine and draped. A 5mm incision was made in the supra umbilical position and a Veress needle was used to create pneumoperitoneum. A 5mm trocar was placed in this position and a diagnostic laparoscopy was performed with a 5 mm 0 degree telescope. Once the pelvis was found to be free from gross abnormality, the decision to proceed with the transvaginal technique was made. The operating surgeon sat between the legs, the first assistant on his right side and the second assistant on the left side of the patient.

A colpotomy on the posterior fornix was made using regular instruments under direct vision (Figure 33 A). Bulging out of peritoneum and subsequent gas bubbles from the already created pneumoperitoneum indicated the opening of the peritoneal cavity. The operating surgeon introduced the blunt contact-view trocar through the colpotomy into the cul-de-sac of Douglas with guidance of both direct contact view of the trocar (Figure 33 B) and the laparoscopic view (Figure 33 C); the metal, 60cm long, 3.3cm diameter trocar was advanced until it reached the upper right abdominal quadrant. The contact viewing system was then withdrawn and the optical system and transvaginal instruments were inserted through the seal of the face plate.

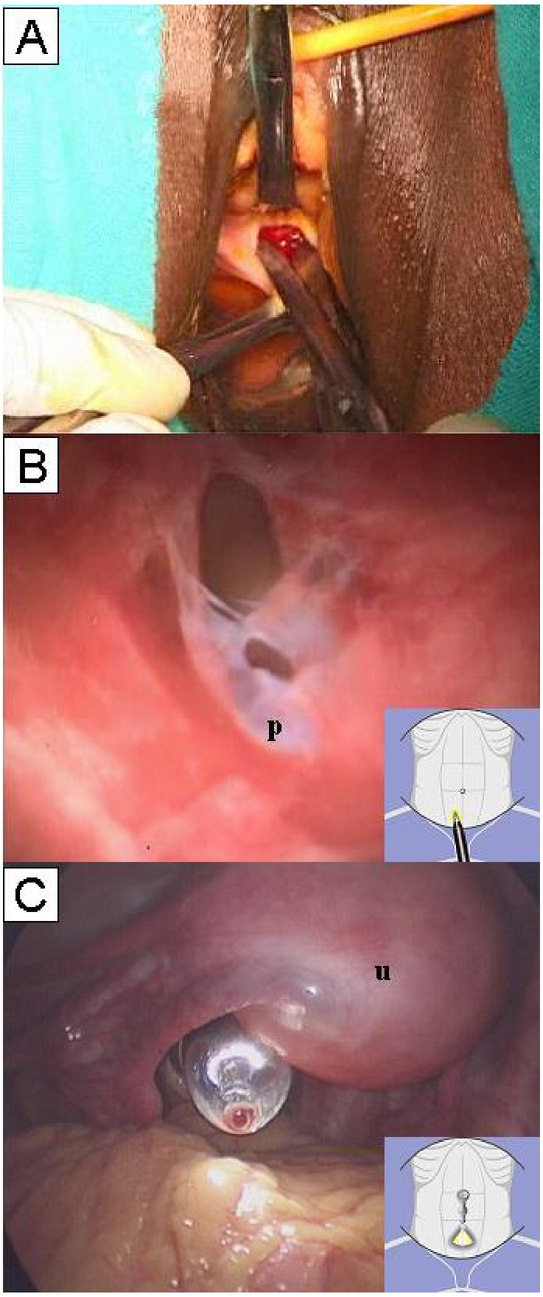


Figure 33. Incision on the posterior fornix (A), entry into the abdomen, the contact view from vaginal side (B), laparoscopic view from the umbilical port (C). p= peritoneum giving way to the optical trocar through the vagina, u= Uterus

The dissection started at the adhesions on the gallbladder fundus (Figure 34 A). The Calot's triangle was dissected with the special long curved/rigid instruments using an atraumatic grasper on the left hand and scissors on the right hand (Figure 34 B). A 5mm grasper was used from the abdominal port to retract the fundus of the gall bladder only if there was no optimal view. The cystic artery was identified (Figure 34 C), isolated and clipped (Figure 34 D) with regular clips mounted on a long clip applicator. After dissection of the artery the cystic duct was dissected with scissors (Figure 34 E) and divided between the clips (Figure 34 F).

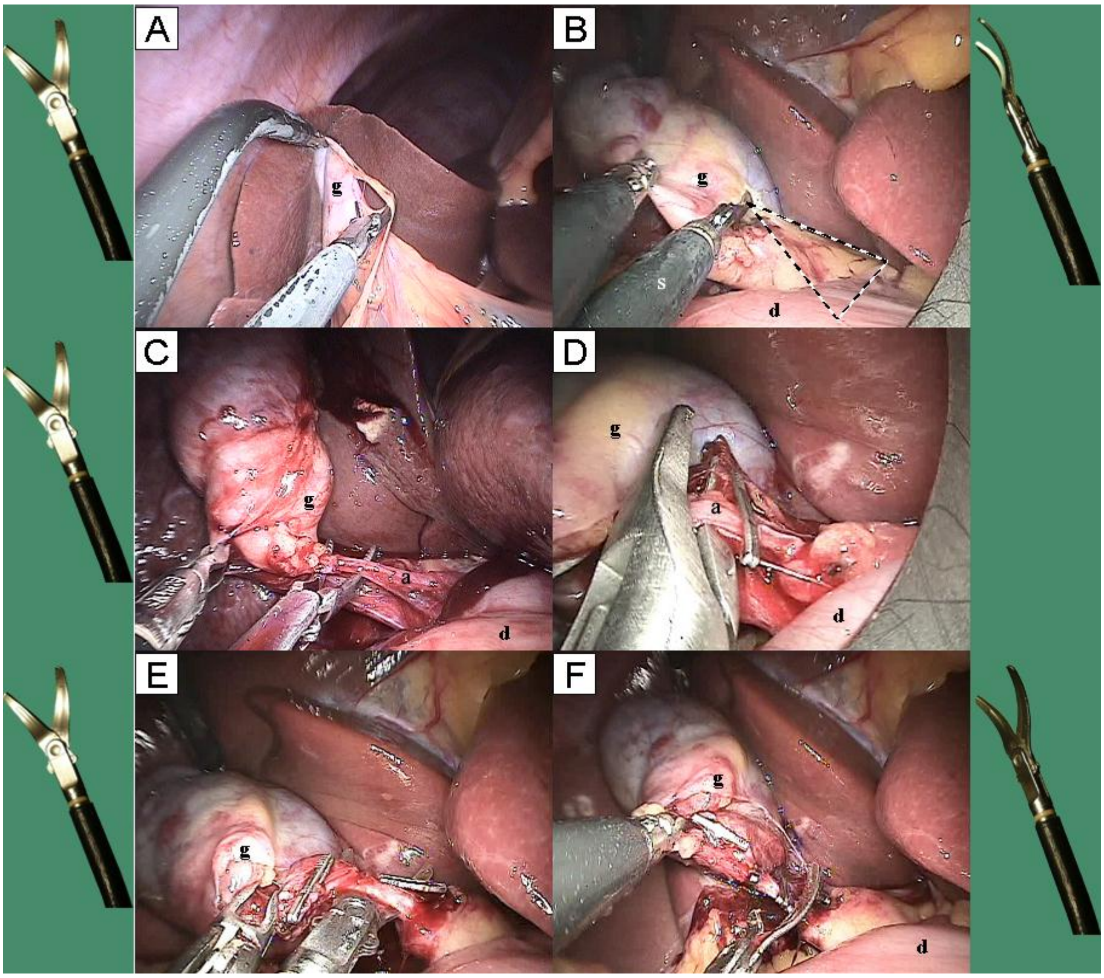


Figure 34. The dissection around the Calot’s triangle with the long steerable instruments. The lateral instrument images explain the rotational position of the instrument tips. g=gall bladder, a=cystic artery, d=duodenum

The gallbladder was separated from the liver bed using scissors (Figure 35 A, B). Haemostasis was achieved using monopolar high frequency current directly through the insulated long suction tube (Figure 35 C). Suction and irrigation canula helped to clean the operative field (Figure 35 D). The gallbladder was removed through the transvaginal port. The transvaginal port was removed under laparoscopic view and the colpotomy was closed under direct vision with absorbable sutures. An attending gynecologist was available during the trans-vaginal access and closure of the colpotomy. The abdominal port was closed with a single skin staple.

Six female patients were successfully operated in the Department of Surgical

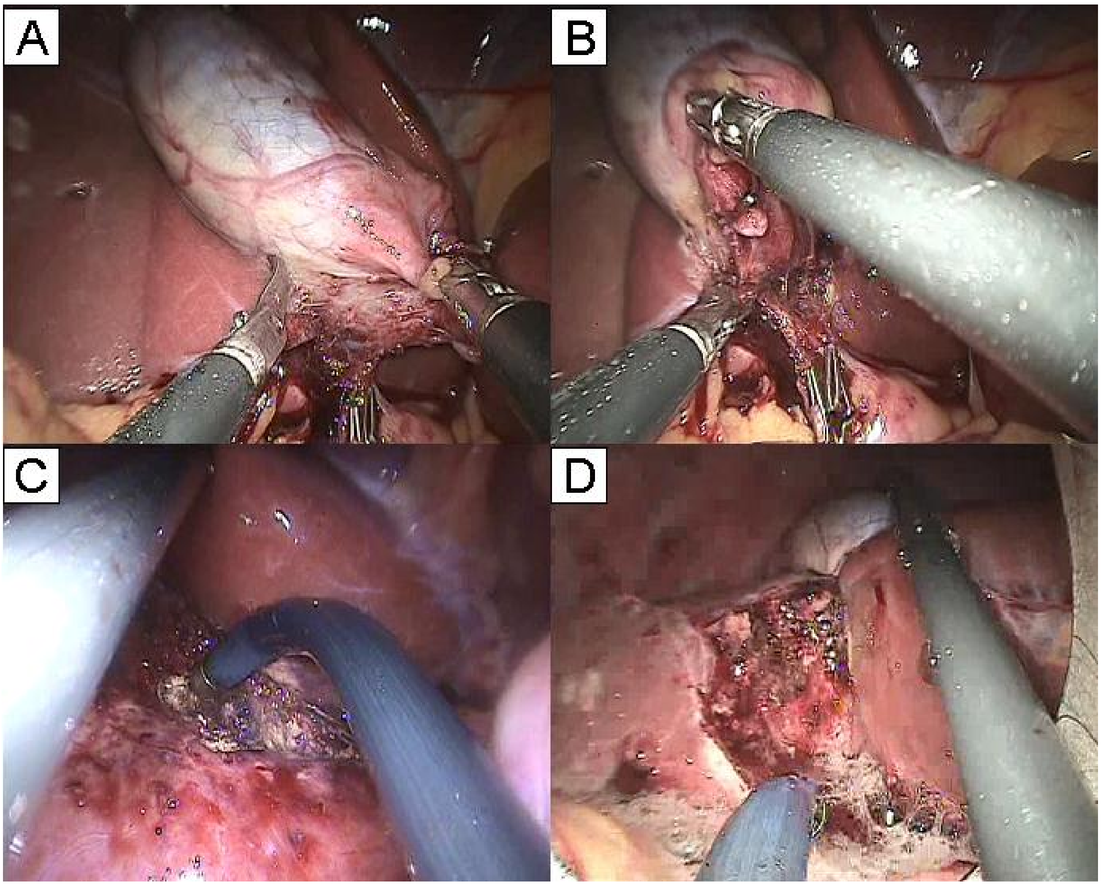


Figure 35. Separation of the gall bladder from the liver bed and haemostasis with the long instruments inserted through the transvaginal port

Disciplines, All India Institute of Medical Sciences, New Delhi, India. The first patient was operated on 25th March 2008. Three surgeons with varying experience in laparoscopic surgery performed the procedures Transvaginal entry into the peritoneal cavity with the long tube was uneventful and was made safely in all cases. The blunt conical tip of the trocar with contact viewing system allowed gradual dilatation of the colpotomy and thus maintained the air tightness throughout the procedure. The contact vision from the trocar demonstrated its safe passage with the separated peritoneum and intact bowel loops at its side. The laparoscopic view, in addition to the contact vision, was an added measure to guarantee the safe introduction of the trocar. Initially we tried to perform the dissection by only using the two working instruments on the vaginal port; however, the fundus of the gall bladder fell back on the dissecting area, hence a grasping forceps was used through the supraumbilical port. This forceps was used only to retract the gall bladder fundus, no dissection was carried out with it.

Adequate triangulation with required traction and counter traction for precise dissection was achieved in all cases. All dissections were carried out with strict adherence to the standard principles of laparoscopic cholecystectomy. There were adhesions with omentum in the second and sixth cases, which were very dense in the latter. The cystic artery and the cystic duct were identified and dissected out in all cases. The cystic artery and duct were clipped with regular titanium clips mounted on a long applicator (10mm diameter) and divided in between the clips. Controlled and precise movement of the scissors was achieved in all cases during dissection and division of the structures. Haemostasis was routinely achieved with coagulation via the long transvaginal instruments in all but one case. There was a spurting bleeding from the cystic artery in the sixth case, which was promptly controlled after application of clips. The gallbladder was separated from the liver bed with scissors attached to a monopolar energy source. In all patients the gall bladder could be dissected out intact with no spillage of bile or stones and in five cases it was removed easily through the tube. In the sixth case it was not easy to bring it into the port due to the large size of the stone and the tumour, but we finally succeeded. Haemostasis was complete in all cases and laparoscopy from the umbilicus after removal of the transvaginal port revealed no abnormality.

The average operating time was 80 minutes including 15 minutes for creation of colpotomy and its closure. The gallbladder dissection time was between 22 to 60 minutes. Intra operative bleeding was less than 50ml in the first five cases and most of it occurred during creation of colpotomy. The sixth case had about 100ml of blood loss due to the difficult dissection and resulting bleeding from the cystic artery. This case subsequently turned out to be a carcinoma of the gall bladder (Table 2).

During the postoperative period three patients had significantly less pain compared to regular laparoscopic cholecystectomy patients, while two experienced similar intensity of pain. One patient had significant pain and distension in the lower abdomen. Ultrasonography revealed collected fluid in the pelvis. On the second postoperative day, her umbilical port was re-opened, a drainage tube was introduced into the pelvis and 500ml of haemorrhagic fluid was evacuated. She recovered well. None of the patients complained of pain in the vagina or had major discharge from it.

Table 2.

Variable	Case 1	Case 2	Case 3	Case 4	Case 5	Case 6
Age (years)	35	29	28	45	30	60
Preoperative symptoms	Abdominal pain	Abdominal pain	Abdominal pain	Abdominal pain	Abdominal pain	Abdominal pain
Previous surgery	Laparoscopic tubectomy			Laparoscopic tubectomy	Laparoscopic tubectomy	Open tubectomy
Operation time (min)	115	75	75	60	40	115
Blood loss (ml)	<50	<50	<50	<50	<50	<50
Post operative pain	Less than laparoscopic cholecystectomy	More than laparoscopic cholecystectomy	Equivalent to laparoscopic cholecystectomy	Less than laparoscopic cholecystectomy	Equivalent to laparoscopic cholecystectomy	Less than laparoscopic cholecystectomy
Final histology	Chronic cholecystitis	Chronic cholecystitis	Chronic cholecystitis	Chronic cholecystitis	Chronic cholecystitis	Carcinoma of the gall bladder

Histopathology report showed chronic cholecystitis in five cases. The sixth case turned out to be a carcinoma of the gall-bladder for which the patient subsequently underwent wedge resection of the liver with portal lymphadenectomy.

At three and six month's postoperative follow-up period, no patient had reported excessive vaginal discharge or other symptoms and there was no visible scar

Figure 36. Six weeks' post operative picture of the patient

(Figure 36). Three patients had sexual intercourse and none reported dyspareunia. The remaining three did not have sexual intercourse for reasons not pertaining to the vaginal interventions.

The success of transvaginal cholecystectomy both in experimental and clinical set ups motivated us to explore the feasibility of major organ resections like recto sigmoid resection through the natural orifice.

2. Materials and methods

2.1. Experimental setup

The research and the developmental work for the project is carried out in the research laboratory of the Section of Minimal Invasive Surgery, Eberhards Karls University, Tuebingen, Germany. The research laboratory is well equipped with a complete operating room (OR) set up. In short, the OR comprises of modular multitask operating table (Stierlen MAQUET, Rastatt, Germany), three high definition flat screen monitors hanging from the roof (BenQ Corporation, Taiwan, China), endoscopic cameras, (Richard Wolf GmbH, Knittlingen, Germany; Lemke, Grobenzell, Germany), illuminator for the endoscopic procedure (Richard Wolf GmbH, Knittlingen, Germany), video recording systems (Sony Video Cassette Recoreder, Sony Corporation, Japan), air insufflations and suction system of TEM and the wide range of hand instruments for open surgery, laparoscopic surgery and transanal endoscopic microsurgery (Figure 37).

Figure 37. The operating room

2.1.1. TEM instruments

The TEM instruments those are used in the project are A. TEM rectoscope, 14.5cm long , 40mm diameter window tube (Figure 1), B. TEM stereo optics (Figure 3), C. TEM hand instruments i.e needle holder, grasper, clip applicator (Figure 4), D. TEM suction and insufflations system, articulating arm for holding the TEM system (Figure 5), F. Curved laparoscopic scissors.

2.1.2. Newer instruments

In the context of Natural Orifice Translumenal Endoscopic Surgery (NOTES), a new set of instruments have been designed for the translumenal intraperitoneal surgeries. These instruments are based on the principles of TEM technology, however, are long and steerable (Figure 25). The prototypes of these instruments have been already used in the experimental and the clinical trials of transvaginal cholecystectomy. In the current project, the new instruments those have been used are, A. Tube, 70cm long and 33mm in diameter, B. Curved steerable hand instruments i.e. scissors and graspers, C. 10mm, 45cm long, 30^0 optics with 90^0 angled upside rear end to avoid collision with hand instruments. The hand instruments have curved effectors like scissors on a curved shaft. The effectors and the shaft are independently rotatable by two wheels located near the handle of the instruments. The operator can rotate the shaft or the effectors by moving these wheels (Figure 27 and 28). Due to the curved rotatable feature of the instrument, a larger operating area can be reach even through the single port system. Figure 29 demonstrates the advantages of these curve instruments over the straight instruments.

2.1.3. Tuebingen MIC Trainer

The dorsal wall of the Tuebingen MIC Trainer is covered with pink paper then with a silicon rubber sheath. The pink paper gives a more realistic colour to the working environment. The silicon rubber sheath aids in fixation of the organs to the trainer. A maroon coloured plastic block is placed in left hypochondriac region of the trainer to mark the area of the spleen.

2.1.4. Integration of animal organs for recto-sigmoid resection

The enblock specimen of young bovine large bowel with attached mesentery, vessels, ureter and peritoneum is collected from the slaughter house. The bowel contents are removed; cleaned with water and the specimen is stored at -23^0 centigrade. On the day of experiment the specimen is removed from freeze and thawed to room temperature. The specimen is checked for the anatomical integrity and if found satisfactory then prepared for the experiment. The peritoneal reflection over the antero-lateral side of the rectum is noted and the rectum is divided 10-12 cm anal to the lateral reflection of the peritoneum. The anal end of the specimen is sutured to a circular plastic ring.

The en bloc specimen is introduced to the trainer. The circular plastic ring which simulate anal verge is placed on the inbuilt anal site of the trainer. The urinary bladder is fixed beneath the pubic symphysis of the trainer. The inferior mesenteric vessels and some portion of aorta are sutured in midline about 3-4cm cranial to the sacral promontory on the dorsal abdominal wall. The ureter is placed in upper pelvis, in lower pelvis more anterior .Some flimsy peritoneal adhesions of the colon are divided to bring the colon from midline to lateral location. The rectum and colon are oriented in human anatomical configuration. The peritoneum is sutured at various sites to the trainer to fix the specimen. The fatty tissue along the lateral wall of the descending colon and upper sigmoid colon is sutured to the trainer; this reproduces the lateral peritoneal attachment

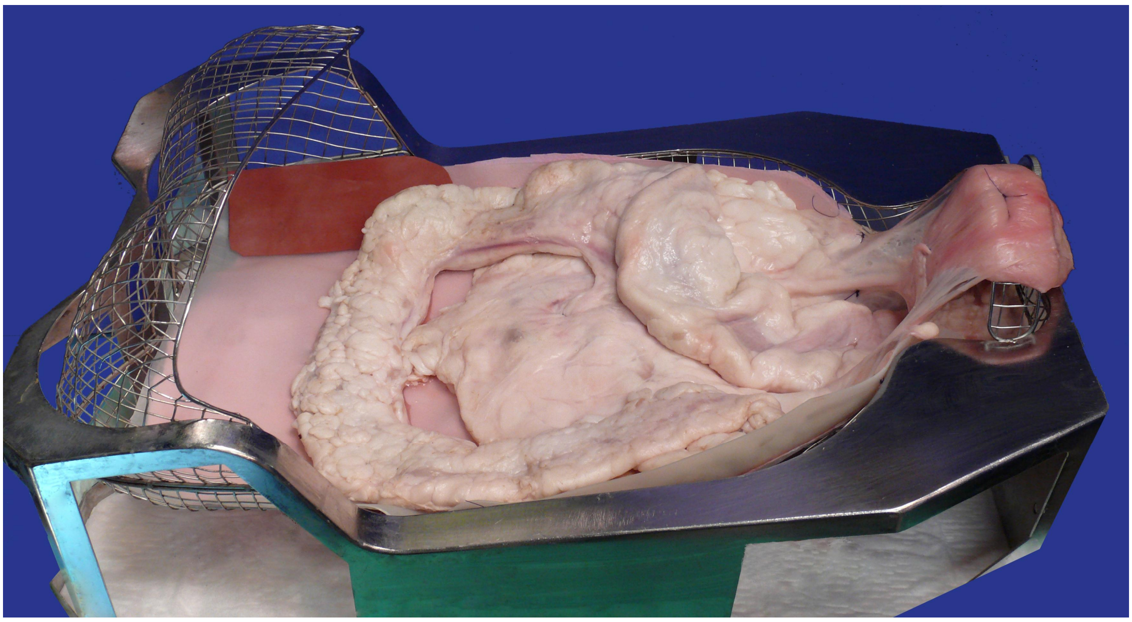


Figure 38. The integrated organ block in the trainer

along the white line of Toldt. The splenic flexure is oriented and fixed with multiple sutures near to the spleen. (Figure 38)

Once the organ block is satisfactorily integrated to the trainer and the anatomical landmarks are reproduced, the proximal end of the colon is closed to prevent the leak of insufflated air. The trainer is then covered and placed on the operating table.(Figure 39, Figure 40)

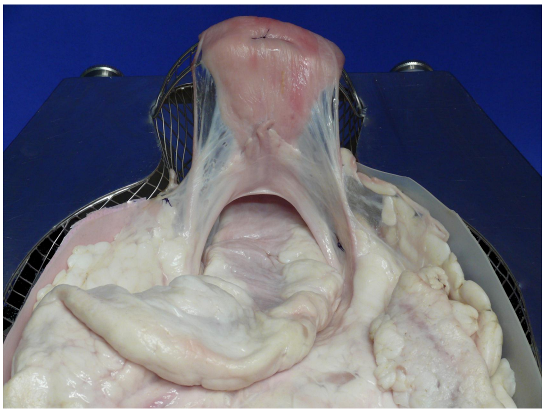


Figure 39. The pevis after integration of the organ block into the trainer

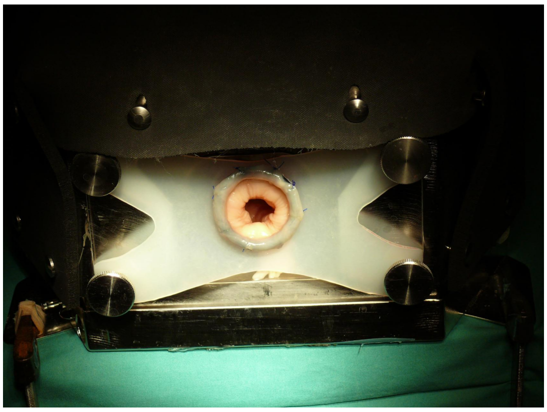


Figure 40. The restructured anus. The circular plastic ring reproduces the anal verge

2.2. Transanal rectosigmoid resection: Evolution of the technique

The present literatures on the topic are critically reviewed and the procedural details for the transanal rectosigmoid resection are planned in concept. Each step of the procedure is tried in different ways and then evaluated to obtain a good standard. In this process, there have been several additions and deletions to the original concept to attain the present status. During the pretrial phase, it was observed that the deep freezing process cause several mechanical and structural damages to the bowel; the bowel mucosa almost got lost, there is loss of tensile and elastic strength of the bowel wall. Also, the calf rectal wall is very thick compared to the human rectum. So, to perform the anastomosis in a more realistic human like situation, the entire experiment is divided into two setups. In the first setup, the complete organ block is integrated to the trainer, all the dissections and the preparations for the anastomosis are made and the specimen is removed; however, the actual anastomosis is not performed in this setup. In the second setup, two segments of bowel are integrated to the pelvis of the trainer as rectum and colon for the anastomosis. The situation is identical to what we left in the first experimental setup, however, the bowel is prepared chemically to minimize the freezing damage and the thickness of the bowel walls are similar to human.

During the evolution of the technique, certain steps of the procedure have undergone modifications for several times, some steps are re integrated and some are no longer used in the present experimental setup.

After more than 100 experiments during the pretrial phase, the technical details of the procedure are standardized and are summarized in the following sub-headings.

2.2.1. Surgical steps of transanal rectosigmoid resection

2.2.1.1. Closure of the rectal lumen

The TEM rectoscope is introduce through the anus. The obturator is removed, optic and the sealing systems are inserted. The rectal lumen is insufflated with gas by the TEM insufflator. The rectal lumen is closed from inside at 10-12cm

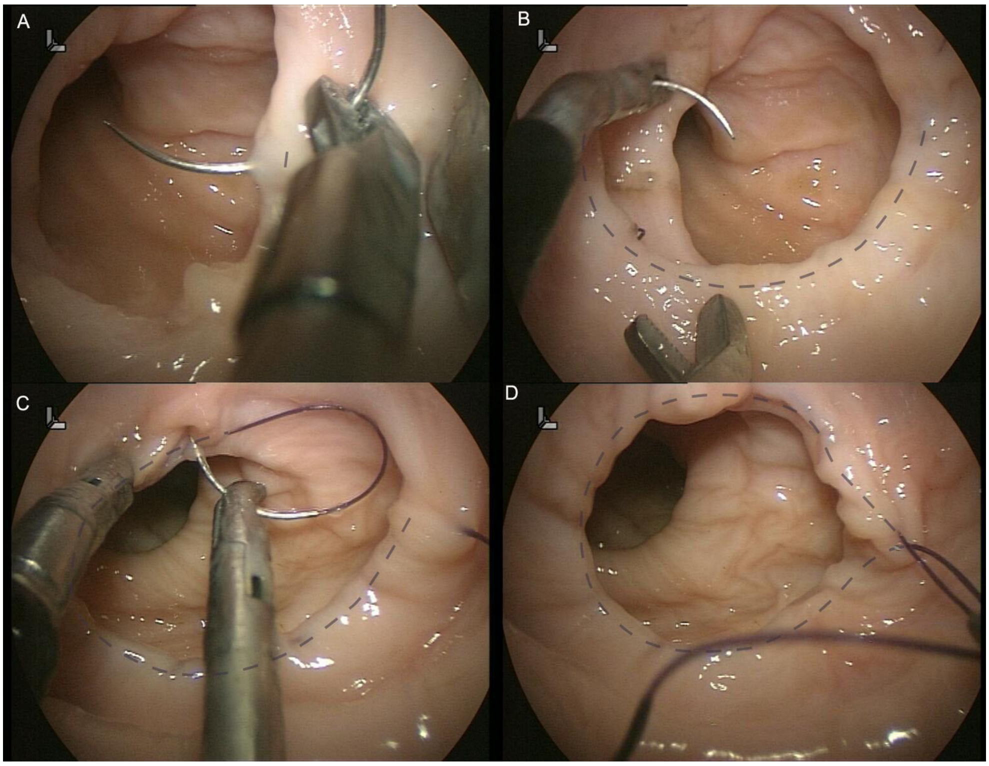


Figure 41. Closure of the rectal lumen by an endolumenal purse string suture

from the anal verge by an internal endolumenal purse-string suture. We use a full length Monocryl 2`O (Johnson & Johnson Intl, St-Stevens Woluwe, Belgium). (Figure 41)

The tail end of the thread remains outside the rectoscope and closure begins with sero-muscular stitch placed at 4 O clock position on the rectal wall. Multiple horizontal sero-muscular stiches are then placed on the same line on the entire circumference of the rectal wall and a vertical circle of purse-string is made. A straight regular laparoscopic needle holder is used during the suturing of the anterior rectal wall. The needle end of the suture is brought out of the rectoscope (Figure 42).

Figure 42. Both ends of the purse string suture are brought out of the rectoscope for closure by the sliding knots

A tampon held with a grasper is introduced to the purse-string and the suture is tied with multiple extra corporeal knots. Thus the rectal lumen is closed over the tampon to maintain adequate water tightness. (Figure 43).

2.2.1.2. Transection of rectum and excision of mesorectal tissue

The rectal mucosa is marked circumferentially with scissors one centimeter anal to the purse-string suture (Figure 43).

The rectoscope is withdrawn by 2cm and rectal intra-luminal pressure is lowered by 3-5cm of Hg; these maneuvers make the anterior rectal wall reachable with scissors and grasper. The anterior wall is then grasped; the layers of the rectal wall are divided sharply on the mucosal markings till peritoneal cavity is entered and continued circumferentially. Anteriorly the peritoneal cavity is opened while on the posterior and lateral sides, the rectum is attached to the mesorectal tissues and the lateral peritoneal attachment (Figure 44)

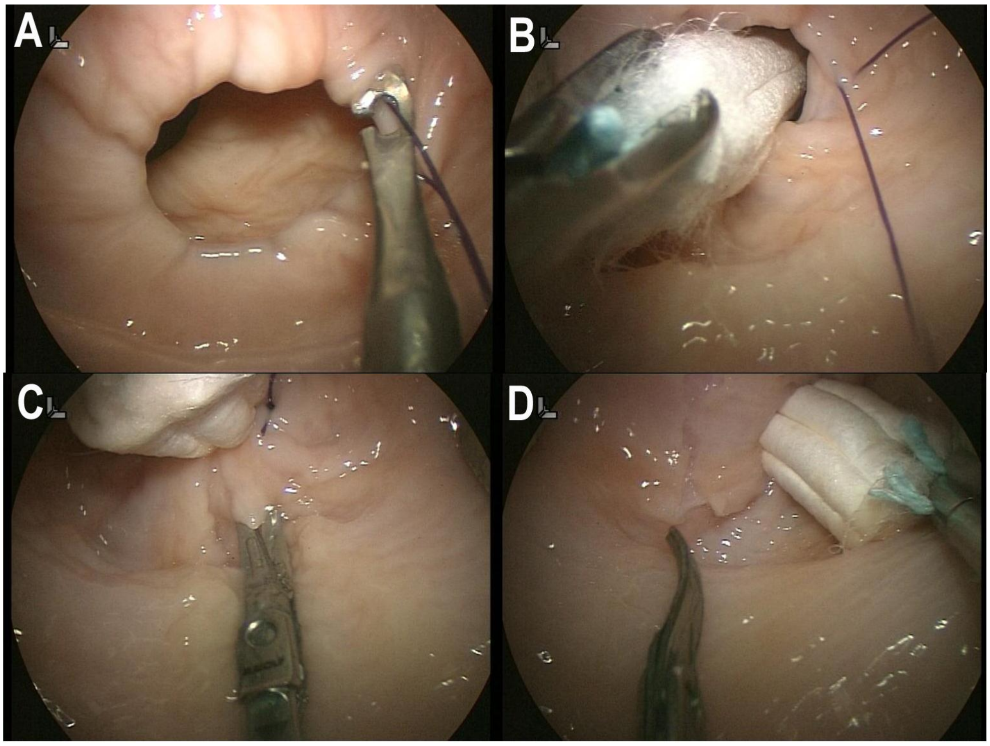


Figure 43. The rectal lumen is closed on a tampon and the rectal mucosa is marked 1 cm distal to it

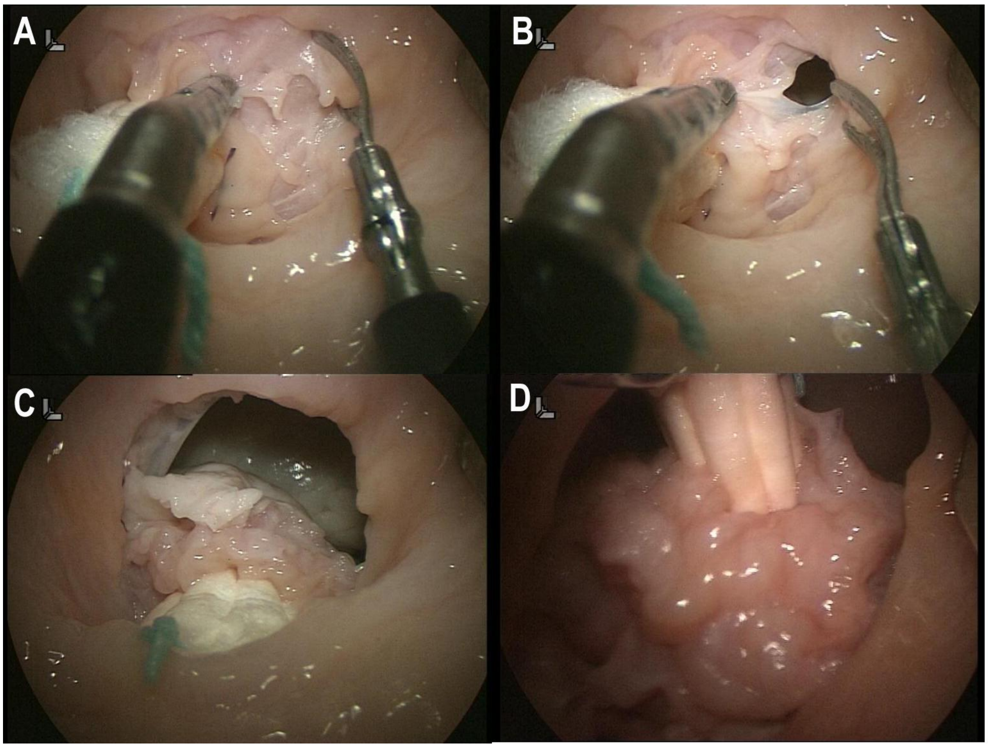


Figure 44. Division of the rectal wall

Mesorectal tissue is excised along the presacral plane and from the lateral pelvic wall. The rectum and the excised tissue is held by the grasper and retracted upward. (Figure 45). This produces adequate traction on the line of dissection. As the dissection proceeds and resected specimen is pushed upward, an unobstructed view of 'empty pelvis' is achieved facilitating precise dissection (Figure 46).

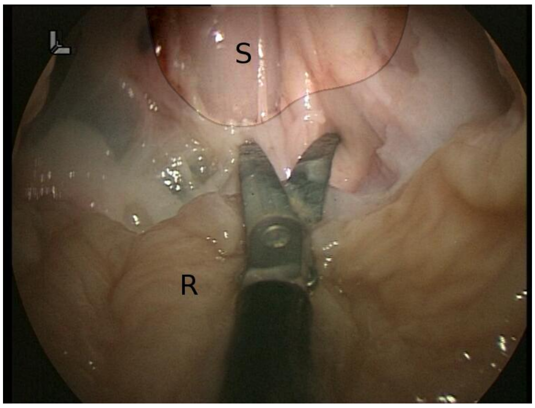


Figure 45. Excision of the mesorectal tissue. R=Rectal wall, S=Specimen end retracted upward

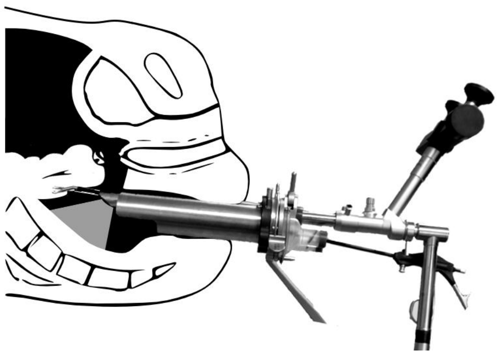


Figure 46. Graphical representation of the empty pelvis view

The left ureter is identified near the pelvic brim. Dissection is continued upto the sacral promontory. The regular TEM instruments do not reach beyond this point; so the resected bowel is placed on the upper pelvis and the TEM system is withdrawn. The long tube is introduced along with the optic and camera, so that its entry into the peritoneal cavity is under visual control; the rectoscope is then positioned near the promontory.

2.2.1.3. Preparation and division of vessels

The dissection continues from the promontory with the long steerable grasper on left hand and the scissors on right hand. The inferior mesenteric artery is identified and dissected out till its origin from the aorta.

The vessel is then held with the grasper and the scissor is removed. The long clip applicator is introduced through the 10mm port of TEM face plate. The artery is clipped thrice. During this step, the assistant needs to hold the rectoscope on his hand and move it according to the need of the surgeon. The scissor is re-introduced and the artery is divided between the clips (Figure 47.)

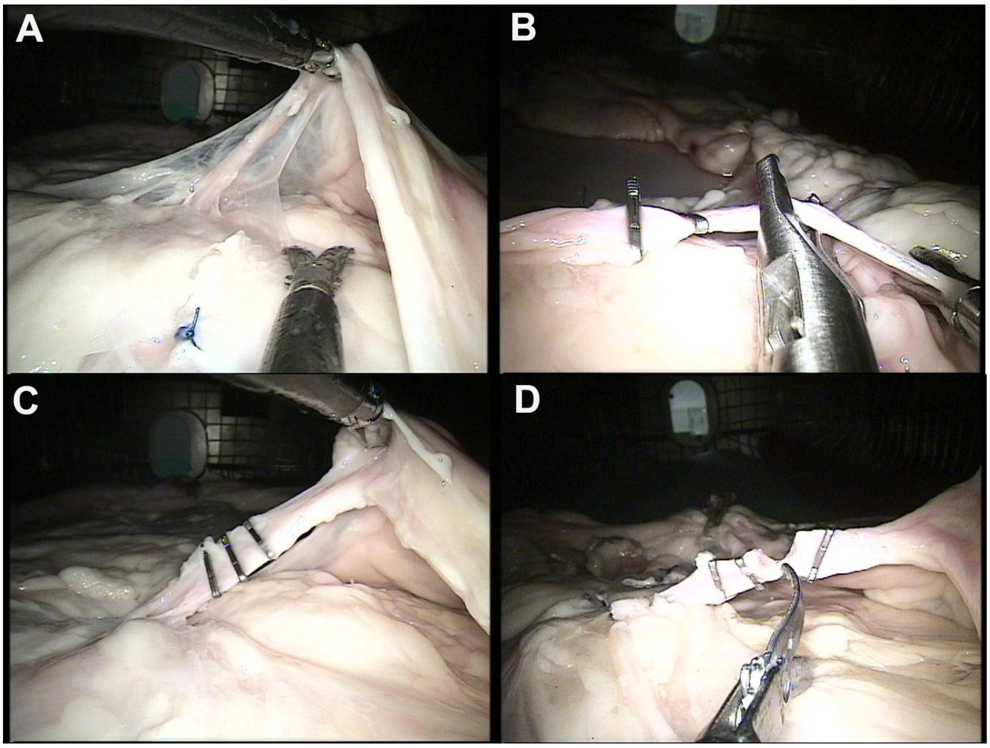


Figure 47. Dissection and division of inferior mesenteric artery

2.2.1.4. Mobilisation of the colon in medial to lateral direction

The dissection is continued laterally and upward separating the mesocolon from the dorsal abdominal wall. The proposed site of resection is defined at the junction of the middle third and lower third of the descending colon. The mesocolon is divided upto this site. The fatty tissue along the medial border at this site is removed to mark the site for future identification (Figure 48).

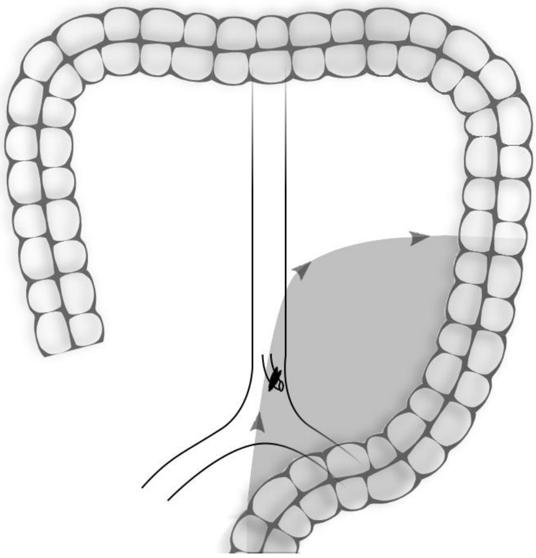


Figure 48. Graphical representation of the medial dissection

2.2.1.5. Moblisation of colon along white line of Toldt up-to the spleen

The rectoscope is brought down to the lateral aspect of simoid colon just above the pelvic brim. The multiple sutured attachment of sigmoid colon to the lateral abdominal wall is removed. The dissection is then continued up to the spleen by dividing the fatty tissue on the bowel wall attached by multiple sutures to the lateral abdominal wall. The splenic flexure is mobilized by dividing the multiple fixation sutures. The complete mobilization of the left colon is checked by free movements of the colon (Figure 49).

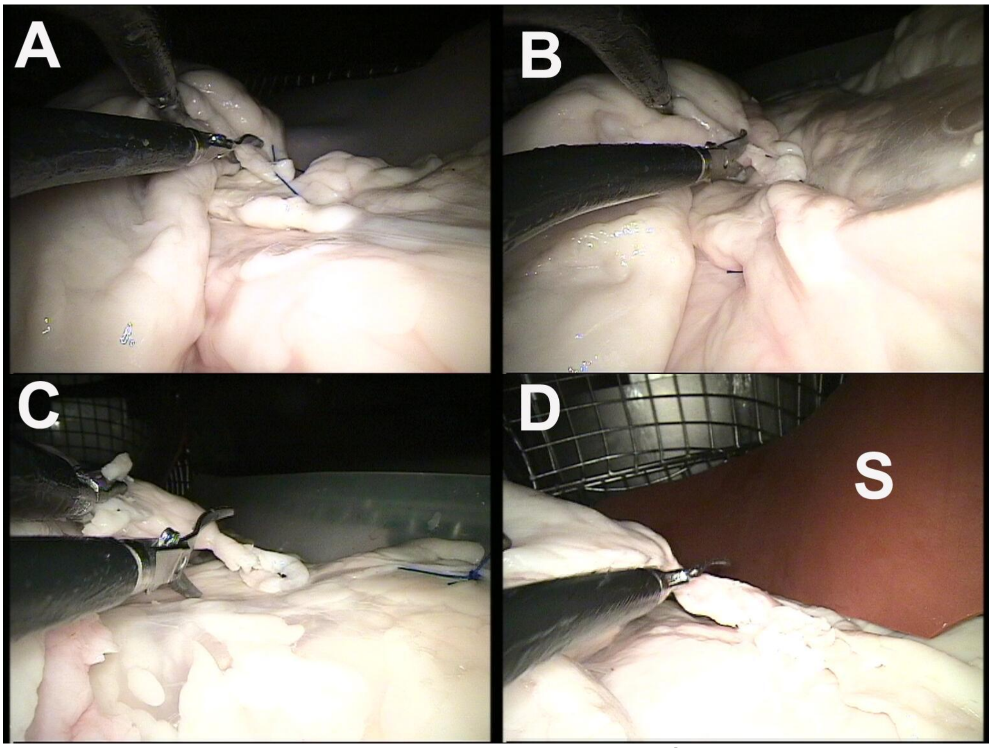


Figure 49. Dissection along the lateral abdominal wall. S=spleen.

2.2.1.6. Preparation for resection and removal of specimen through the anus

The long instrument systems are removed and the regular TEM system is re-introduced. The mobilized colon is brought down to the pelvis. The already marked site for bowel resection is identified. The site is placed close to the rectal stump and feasibility for a tension free anastomosis is judged. The remaining redundant fat from the bowel wall at the site of anastomosis is removed. The prepared bowel is looped by a 2`O Prolene suture e; a sliding GEA knot (75) is prepared outside the rectoscope and the knot is pushed in to occlude the colonic lumen (Figure 50 and 51) This first sliding knot is placed on the lower part of the prepared segment of the bowel. Another sliding knot is placed about 1 cm proximal to the first one. The prolene suture of the second suture is kept long and tail end remained outside. The colon is divided between the knots.

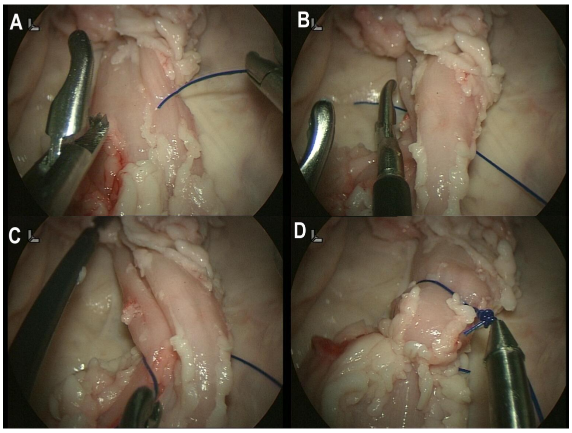


Figure 50. Looping of the colon by a thread

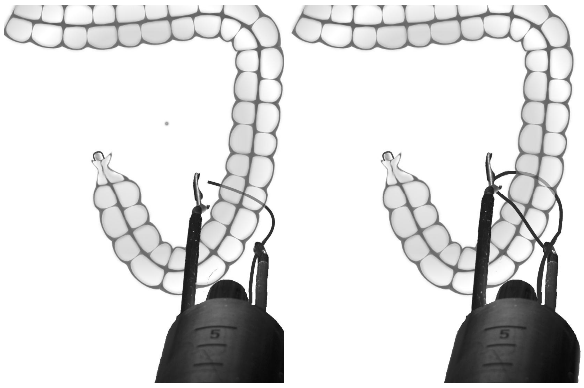


Figure 51. Graphical representation showing how the colon is looped with a thread

The recto-sigmoid specimen is removed through the rectoscope (Figure 52). The rectoscope is withdrawn by 2cm to gauge the approximate diameter of the rectal stump. Accordingly, the colon is divided obliquely above the prolene knot from mesenteric to ante mesenteric border minimizing the discrepancy of diameter between the two segments. The portion of the resected colonic tissue with the thread is removed. The two bowel edges i.e. the colonic edge and rectal edge are checked for anatomical integrity, bowel orientation and adequate approximation for an end to end colo-rectal endoluminal anastomosis (Figure 53).

Figure 52. Specimen removal through the rectoscope

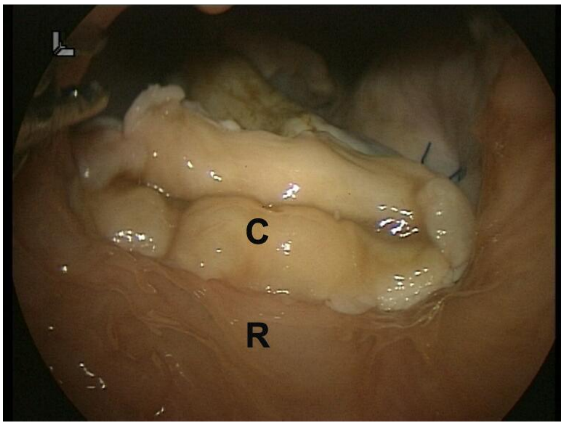


Figure 53. The rectal edge (R) and the colonic edge (C) after removal of the specimen

In a subset of experiments, after removal of the specimen a detachable bowel clamp (Aesculap AG, Tuttlingen, Germany) is placed on the colon above the ligature (Figure 54).

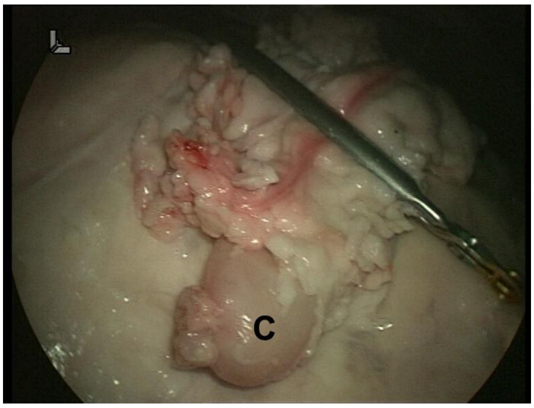


Figure 54. Detachable bowel clamp is placed over the colon. C= Terminal end of the colon

The bowel clamp is then removed after the colon is prepared for the anastomosis as described above. The cover of the trainer is removed to see orientation of the colon, inadvertent injury to the remaining bowel and the rectal stump. The anastomosis is performed subsequently in another experimental setup.

2.2.2. Chemically prepared bowel setup for endolumenal colo-rectal anastomosis

According to our initial experience, the frozen then thawed bowel is not optimal for objective evaluation of an anastomosis. To reduce the thermal damage caused by freezing process; the bowel needs chemical stabilization (See- Transanal rectosigmoid resection: Evolution of the technique, page 46). So a separate setup with chemically prepared bowel is made for the anastomosis part of the operation.

Bovine large bowel with comparable diameter to human is collected from the slaughter house. The redundant fat around the colon at the proposed site of anastomosis is removed. The segment is then cleaned, washed and prepared chemically as follows. The bowel lumen is filled with 4% formaldehyde and allowed to be in contact for 40 minutes; it is then removed and rinsed with water. The bowel is then filled and soaked in a solution of 85% glycerol and 99% alcohol (3:1) for 1 hour 15 minutes. The prepared bowel is then transected at the proposed site of anastomosis and two segments of different diameters are paired and kept in the freezer at -23^0 centigrade. On the day of experiment the segment is thawed to room temperature and allowed to rehydrate in water for one hour. This systematic way of chemical preparation was developed recently by our group. The mucosal cells being very high in water content, expand in volume and burst when frozen. The other layers of the bowel also suffer varying degrees of damage from the freezing process. The solution limits the freezing injury and protect to certain extent the elasticity, tensile strength and mucous layer of the bowel wall.

The rectal portion of the bowel is kept 10-12cm long and the distal end of it is secured to a plastic ring of 4cm diameter to reproduce the anal verge. It is integrated in to the pelvis of the trainer and fixed to the dorsal pelvic wall with multiple sutures (Figure 55). The proximal colonic segment is placed free near to the rectal stump. The outer circumference of the cut edge of the rectum and colon is measured three times and the average is taken after converting it to the decimal of 0.5cm. A difference of at least 1cm is maintained in the circumference of the anastomotic segments.

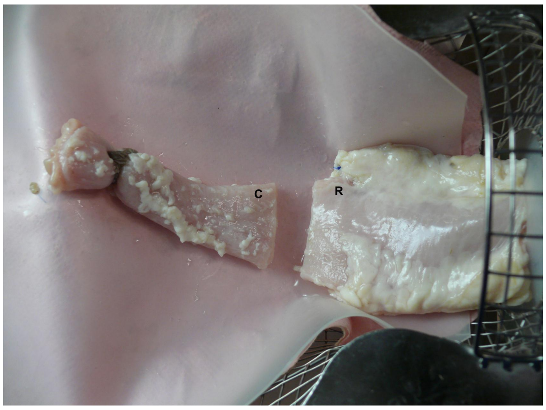


Figure 55. Prepared segments of the rectum (R) and the colon (C)are positioned in the pelvis of the trainer for the anastomosis

For stapled anastomosis, the circumference of the bowel had to be kept below 13cm. This restriction was necessary so that the specific size of stapler could be applied.

2.2.3. Technique of endolumenal end-to-end colorectal hand sewn anastomosis

The TEM system is introduced; the cut end of the rectum and colon to be anastomosed are checked for accessibility and discrepancy in diameter. The circumference of the bowel ends is divided in four imaginary quadrants; 3 to 12, 12 to 9, 9 to 6 and 6 to 3 o' clock positions. The suture length is kept 12cm with a silver clip at the end of the suture. The length of the stay suture is 25cm. The anastomosis performed is end to end by single layer full thickness sutures in four quadrants. The suturing process begins at 3 o' clock position. The rectal wall is grasped with the assistance from the curve of the needle. The rectal wall is held by grasper on left hand and the needle passes out from mucosa to serosa on rectal side then from serosa to mucosa on colon side. Suturing continues from 3 to 12 o' clock position (Figure 56).

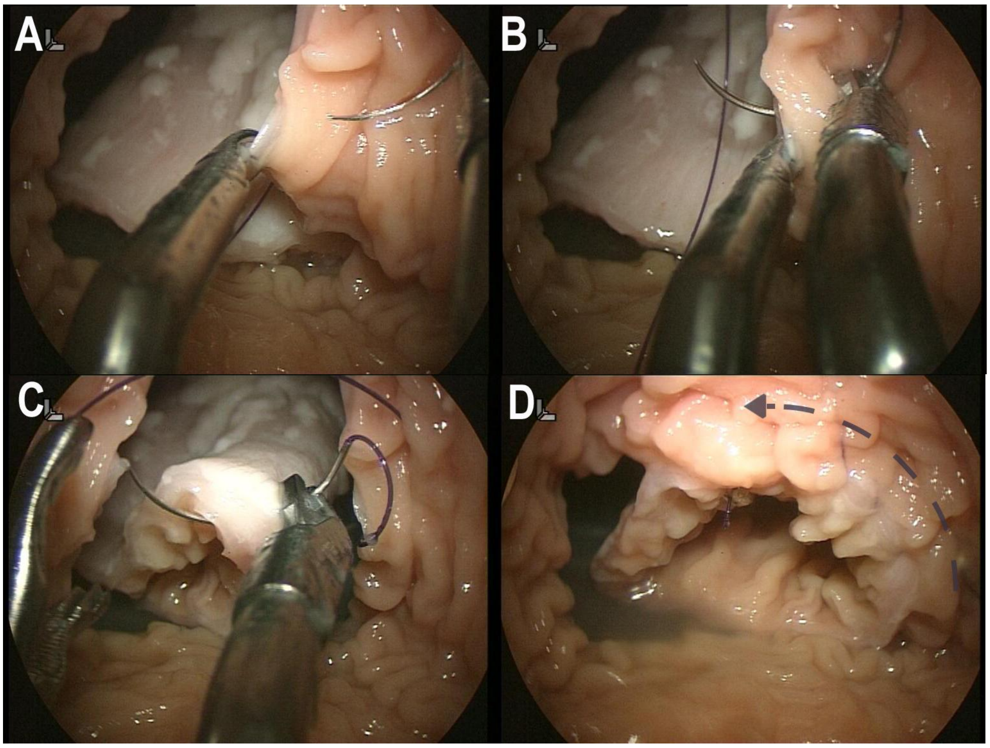


Figure 56. Anastomosis on the first quadrant (3 to 12 o'clock position)

The rectoscope is withdrawn by two centimeter allowing the anterior rectal wall to fall in front of the rectoscope. Each suture is placed around 3-5mm apart and similar distance from the cut edge. After every two or three stitches, the thread is pulled with care to keep the mucosa inverted. At 12 o' clock position, the suture is tightened and divided after applying a silver clip. The second suture is started at 9 o' clock position; needle passing from colon to rectal wall in the same way as earlier. Anastomosis is continued upward till 12 o' clock position. In this position, just near to the previous clip, the suture is tied and a silver clip is applied (Figure 57).

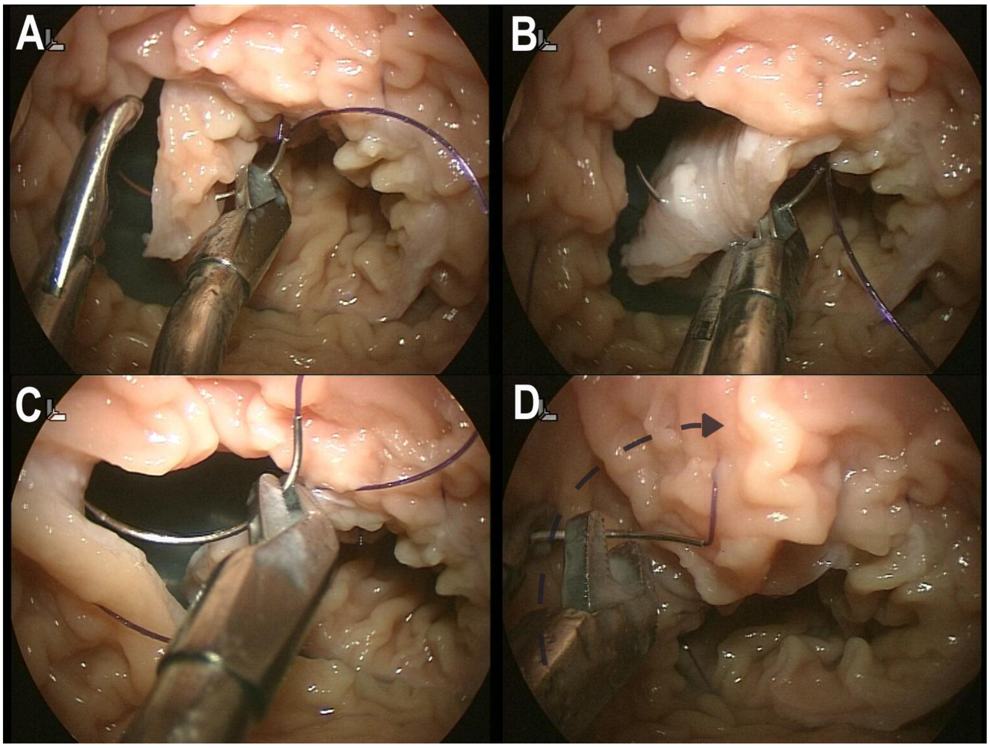


Figure 57. Anastomosis on the second quadrant (9 to 12 o'clock position)

Once the anterior hemicircle is completed, the edges of the bowels are checked for disparity. A U-shaped stay suture is placed at 6 o' clock position. One end of it is kept long and brought out through the middle port on the face plate of the rectoscope. (Figure 58 and 59)

The stay suture helps to approximate the mid point of both the colonic and rectal wall and keeps them parallel (Figure 59 and Figure 60).

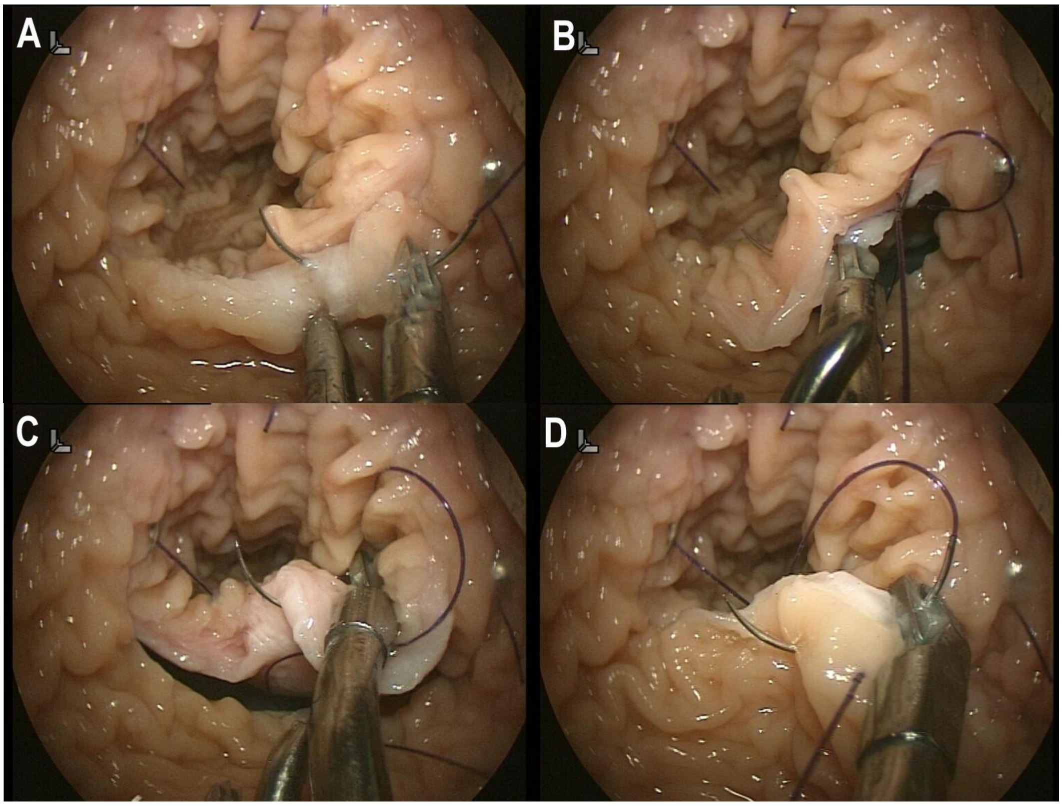


Figure 58. The inverted U shaped stay sutrue, direction of the needle, mucosa to serosa on rectum (A), serosa to mucoas on colon (B), mucosa to serosa on colon (C), serosa to mucosa on rectum (D)

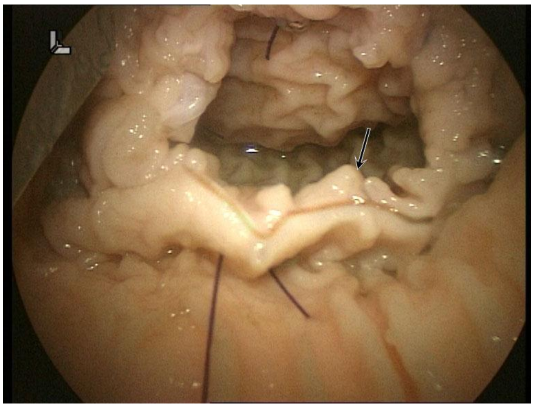


Figure 59. The parallel position of the bowel wall

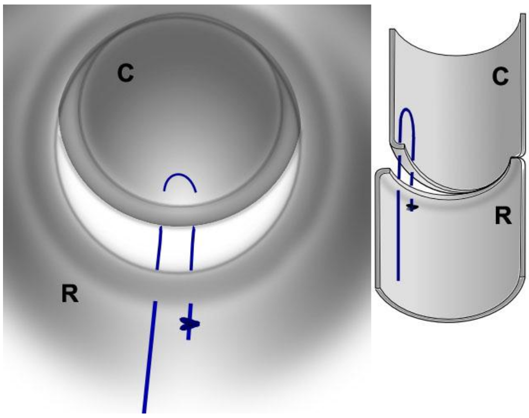


Figure 60. The graphical representation of the stay suture. The endolumenal view and the cross sectional view C=Colon, R=Rectum

The third suture is begins at 9 o' clock position and continued downward till 6 o' clock position. The final suture starts at 3 o' clock position just near to the first suture and continued downward to 6 o' clock position. (Figure 61)

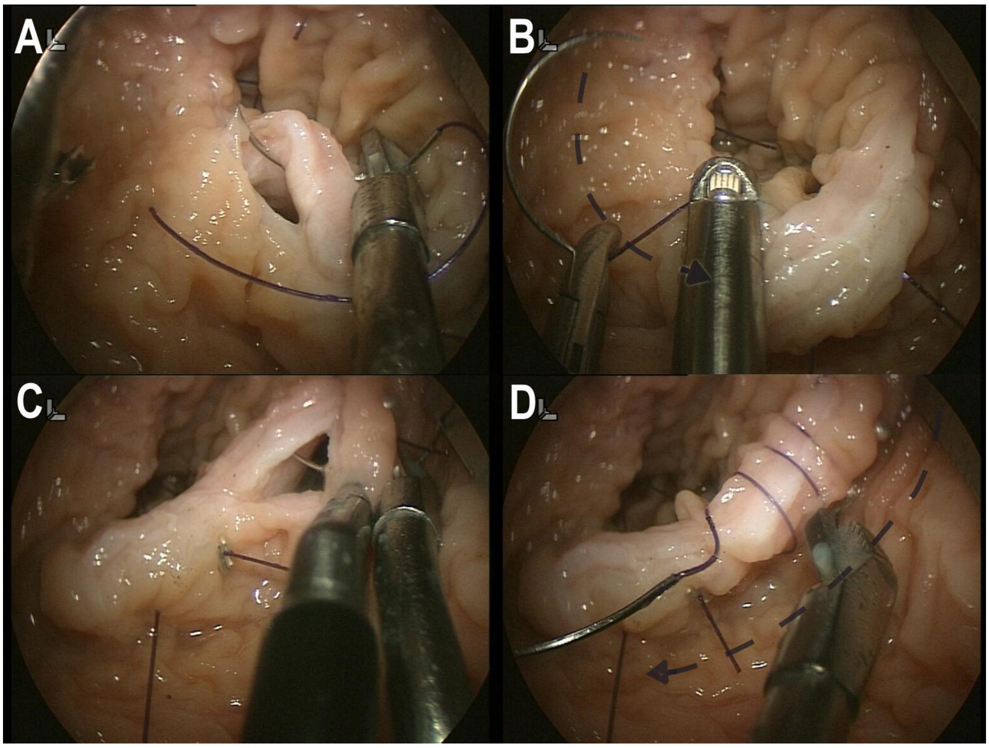


Figure 61. Anastomosis in the 3rd and 4th quadrant

At the end, the anastomotic line is inspected; if some segment is found loose, the tail end of the suture is pulled and an extra clip is applied. The stay suture is cut and removed at the end.

The anastomosed segment is then brought out of the trainer for evaluation of the quality of the anastomosis.

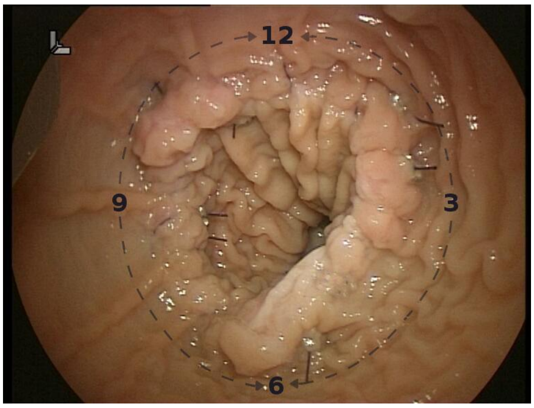


Figure 62. The complete anastomosiss. The arrow represents the direction of suturing

2.2.4. Technique of endolumenal end-to-end colorectal stapled anastomosis

2.2.4.1. Preparation of the stapler anvil and the anvil introducer

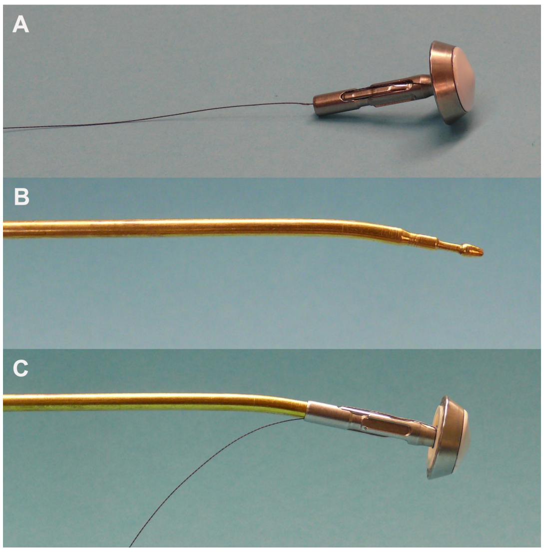


Figure 63. The anvil tied with a thread (A), the introducer (B), the anvil and the introducer assembly

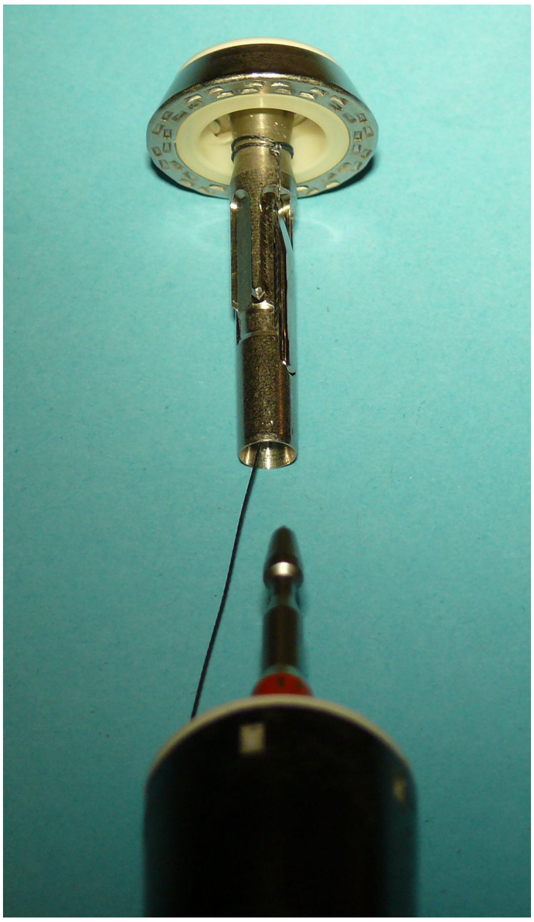


Figure 64. The thread tied to the anvil is brought of the lumen of the anvil post

The anvil head is tied by a thread of 25cm length and brought out through the lumen of the anvil post (tube of the anvil). An introducer is designed to insert the anvil in to the bowel lumen. This introducer has a specific curve at its end (Figure 63). For easy coupling of the anvil post with the trocar of the stapler, it is important to bring out the thread through the lumen of the of the anvil post (Figure 64).

2.2.4.2. Technical details of the stapled anastomosis

The transected end of the colonic segment is sewn circumferentially with a 2 O Monocryl (purse string suture). The tail end of the suture is kept outside the rectoscope and after completion of the purse string, the needle end is also brought out through the same port of the rectoscope. The stapler anvil mounted on the introducer is brought to the pelvis through the rectoscope. The anvil is first inserted partially to the colon, it then stabilizes the bottom half of the colonic wall against the dorsal pelvic wall. With the other forceps on right hand the rest of the colonic wall is glided over the anvil to complete the insertion of the anvil to the colonic lumen. The purse string suture is tied on the anvil post by multiple extracorporeal knots. The introducer is released from the anvil and the anvil secured in the colonic segment is kept free in the pelvis (Figure 65).

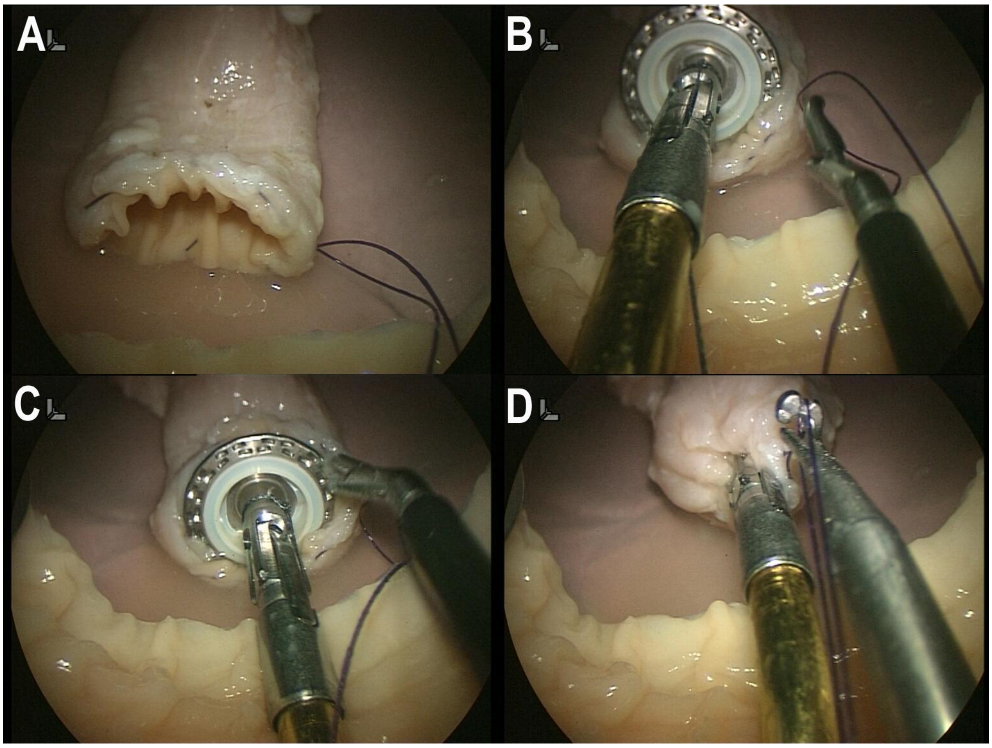


Figure 65. The colon is sewn with by a purse stirng suture (A), the anvil is partly introduced to it (B), the remaining wall of the colon is glided over the anvil (C), anvil is secured with the colon is by sliding knots (D)

The rectoscope is withdrawn till the cut edge of the rectum is visible and the cut edge of the rectum is sutured circumferentially by 2 O Monocryl. Suturing begins at 4 O clock position and continued towards right then towards the left up to the original stitch. The needle is brought out of the rectoscope through same port as introduced before and the both ends of the suture are kept outside the rectoscope. The thread tied to the anvil is pulled to bring the anvil post inside the rectal purse string. The purse string is tied by several extracorporeal knots. Thus, the rectal and colonic ends are tied close to each other over the anvil post. (Figure 66, 67).

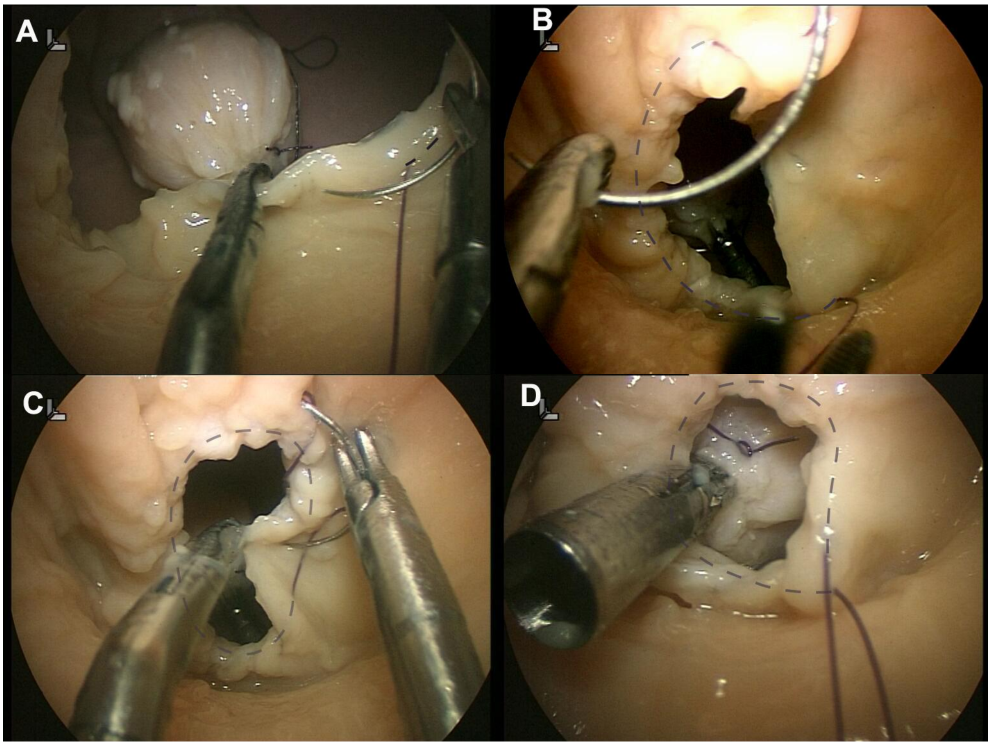


Figure 66. Edge of the rectal stump is sewn by a purse string suture

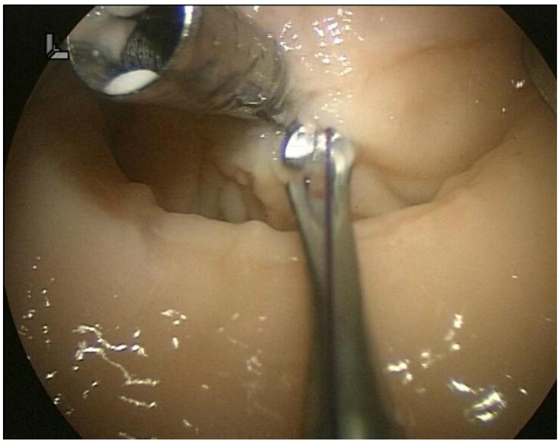


Figure 67. The purse string suture on the rectal stump is tied over the anvil post

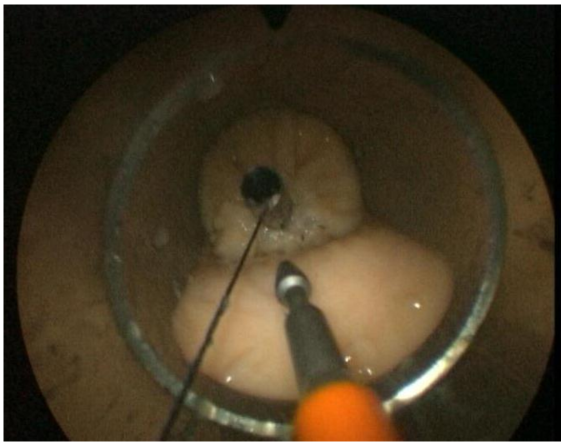


Figure 68. The anvil post is pulled towards the anus and is mated to the stapler

The face plat of TEM is removed and the circular stapler gun is introduced through the rectoscope. A 5mm optic is inserted parallel to the circular stapler. The anvil post and the trocar of the stapler are mated under endoscopic guidance (Figure 68). The thread tied to the anvil post is pulled to fix the anvil to the trocar of the stapler (Figure 69). An audible click marks completion of the process. The stapler knob is rotated to lock the anvil to the gun and stapler is fired. The stapler is removed gradually and the anastomosis is checked with the endoscope (Figure 70).

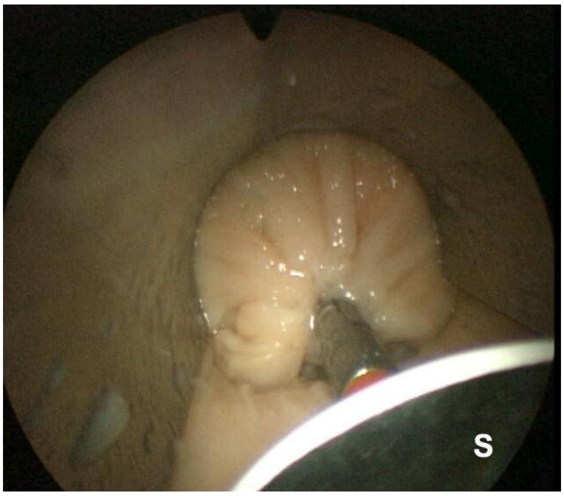


Figure 69. Stapler is mated and anastomosis is being performed. S=Stapler head

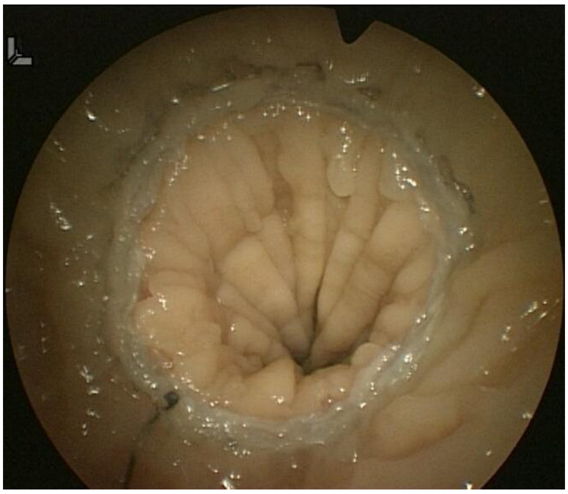


Figure 70. The complete anastomosis

The anastomosis is then carefully removed from the trainer and looked for gross abnormality or obvious defects. The external diameter of the anastomosis is measured and the average of three measurements is taken after converting it to the decimal of 0.5cm. The anterior surface (i.e. 3-12-9 o' clock position) and the posterior surface (i.e. 9-6-3 o' clock position) of the anastomosis are then photographed separately and the anastomosis is prepared for acute pneumatic leak test. In case of stapled anastomosis, the doughnuts are checked for their completeness.

2.3. Set up for acute pneumatic leak test

The colonic end of the anastomosis is closed with a clamp. A cannula is inserted to the rectal end and secured by tying the bowel around it to achieve an airtight seal. The cannula is then connected to a digital barometer, which gives continuous measurements in mbar. The anastomosis is then submerged in water in a tray with a mirror in the bottom that permits accurate visualization of the air bubbles leaking from the posterior side of the anastomosis. Each acute pne umatic leak test is video recorded and the exact pressure ins ide the system in mbar at the moment of the first bubble is checked later by using frame by frame evaluation (Figure 71 and 72).

Figure 71. Arrangement of measuring the acute pneumatic leak pressure.
A= container with water, B=mirror

Figure 72. The arrangement for video recording the acute pneumatic leak pressure test

2.4. Evaluation of the dissection part

The following objective parameters are evaluated after the dissection.

A. Time of the procedure

B. Length of the specimen

C. Inadvertent injury to the colon

D. Position of the tempon

2.5. Evaluation of the hand-sewn anastomosis

The following parameters are evaluated to see the quality of the anastomosis

A. Outer circumference of the rectal and colonic end for the anastomosis.

B. Outer circumference of the bowel at the anastomotic site.

C. Time required for the each quadrant of the anastomosis.

D. Total time required for the anastomosis.

E. Number of spots (area of a single stitch) with visible mucosa on the anastomotic line.

F. Number of spots with serosal defect but without mucosal eversion.

G. Total number of stitches in each quadrant of the anastomosis.

H. Total number of stitches in the anastomosis.

I. Acute pneumatic leak pressure of the anastomosis

2.6. Evaluation of stapled anastomosis

A. Outer circumference of the rectal and colonic end for the anastomosis

B. No. of spots with visible mucosa on the anastomotic line

C. No. of spots with serosal defect without visible mucosa.

D. Time required for the purse-string suture on the colon.

E. Time required for securing the anvil.

F. Time required for the purse-string suture on the rectum.

G. Time required to securing the rectum on the anvil post.

H. Time required for mating of the stapler anvil and anastomosis.

I. Total time for the complete anastomosis.

E. Completeness of the doughnuts.

F. Acute pneumatic leak pressure of the anastomosis.

2.7. Data analysis

Data are analysed using statistical software JMP 8. (SAS Institute Inc, USA). Statistical test used are one way ANOVA, Tukey-Kramer test, t-Test and Wilcoxon Test. P value less than 0.05 is taken as significant.

3. Results

After a series of more than one hundred experiments the technique for transanal rectosigmoid resection was standardized. The standardized technique was then evaluated in two experimental set ups. In the first experimental set up, twelve transanal rectosigmoid resections up to the preparation for colorectal anastomosis were performed. In the second experimental set up, twenty seven hand sewn and twenty stapled anastomosis were performed. Two surgeons performed the procedures. Surgeon A is an experienced colo-rectal (open and laparoscopy) and TEM surgeon. Surgeon B is a novice in colorectal surgery and had no experience in TEM. He underwent the intensive training course for TEM organized by the department before joining this project.

3.1. Face validity of the animal model

The size of the young bovine large bowel is similar to that of human and the integrated organ block on the trainer reproduces close resemblance to human anatomical situation. Several general and colo-rectal surgeons who visited our centre did direct evaluations of the model and agreed that the model had visual, spatial and physical correlation with the human anatomy of the lower gastrointestinal tract. In contrast to this, the living pig does not allow the transanal access we need and the anatomy is not comparable to human. The long instruments reach easily upto the splenic flexure. The operating surgeon had no difficulty in manipulating the instruments through the long tube; although, there were conflicts between the long instruments or between the instruments and the optic. These conflicts were encountered in various magnitudes in all the procedures; however, the operating surgeon did not consider them to be significant enough to influence the safe performance of the procedure.

3.2. Transanal rectosigmoid resection

The transanal mobilization and resection of the upper rectum and sigmoid colon were performed in twelve experiments. Adequate closure of the rectal lumen by the endolumenal purse string sutures were achieved in all the cases. A straight regular laparoscopic needle holder was very useful in placing the stitches on the anterior rectal wall. The tampons could be placed without difficulty into the purse string suture in all the cases. The average time required for placement of the purse string and securing the tampons was 14.36 min.

The transection of the rectum and the dissection of the mesorectal tissue were uneventful and the left ureter was identified and preserved in all cases. As the dissection progressed in a retrograde fashion and the specimen being retracted upward, completely away from the operating field, an empty pelvis was obtained providing a good overview of the operating field (Figure 45 and 46).

Clipping of inferior mesenteric vessels were difficult in two cases. In these cases, multiple attempts were needed to position the jaws of the straight clip applicator over the artery and to clip it. During clipping of the artery, the assistant holds the rectoscope with his hands and move it according to the position of the artery. This help was required in all the cases.

The descending colon was mobilized upto the splenic flexure and the specimen delivered through the rectoscope.

The detachable clamp was placed from antemesenteric to mesenteric border in the last three cases. Its application and removal was uneventful. There was no spillage of colonic content during removal of the specimen and the tampons were well secured on the resected specimen.

The evaluation after the procedure by removing the cover of the trainer revealed that the colon was aligned properly in all the cases. Both the rectal stump and colon were prepared adequately for the anastomosis.

The operative time distributions during the different steps of the procedure are shown in table 3.

Table 3.

Operative step	Range (min)	Mean (min)	SD	95% CI
Placement of purse string suture and securing the tampon	11.4-19.4	14.36	2.6	12.7-16.1
Division of the rectum and mesorectal dissection	12.6-19	18.02	3.37	15.9-20.2
Dissection above the promontory with the long instruments *	12.7-27.8	21.27	4.12	18.7-23.9
Specimen removal and preparation for anastomosis	18.75-35.3	24.98	4.67	22.1-27.9
Total time	64.4-96.5	78.65	9.9	72.4-84.9

SD=Standard deviation. CI= Confidence interval.

*Dissection and control of the vessels, mobilization of descending colon and the splenic flexure.

The average length of the specimen was 37.2cm. (Range 31–46 cm) (Figure 73). There was no injury on the resected specimen.

Figure 73. The resected specimen

3.3. Endolumenal hand sutured colorectal anastomosis

Twenty seven end-to-end endolumenal colorectal anastomoses were performed. One operation was not video recorded due to a technical problem of the recorder; hence twenty six procedures were analyzed. Figure 74 and 75 shows the external view of the anastomosis.

Figure 74. The external view of hand sutured anastomosis (Anterior surface)

Figure 75. The external view of hand sutured anastomosis (Posterior surface)

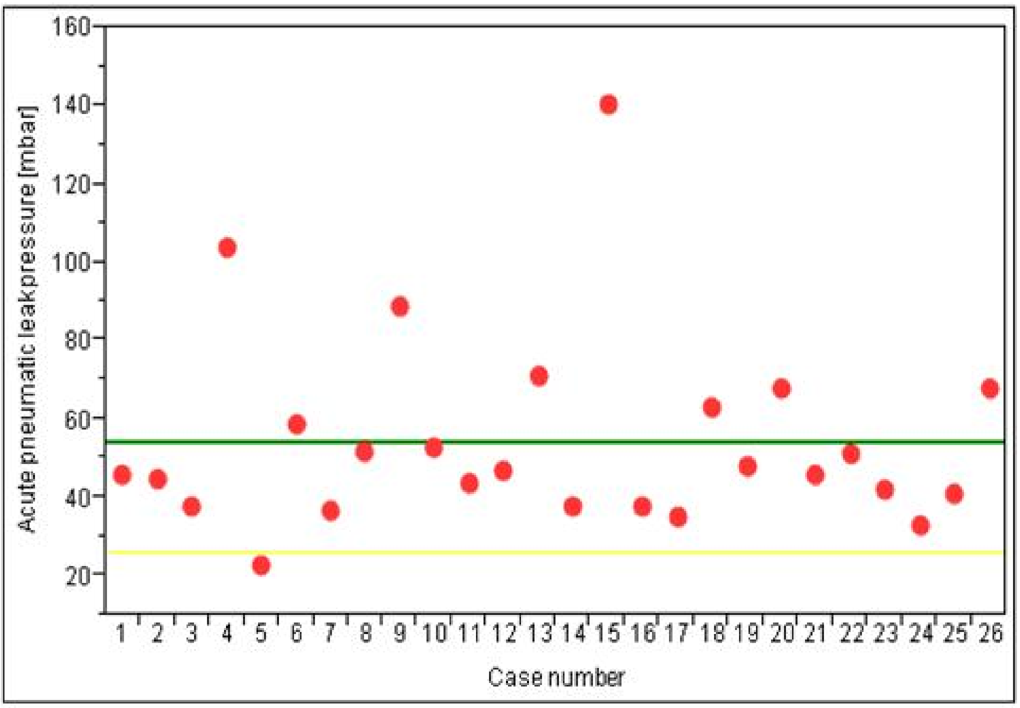
The main results hand sutured endolumenal colorectal anastomosis are summarized in table 4

Table 4:

Variable	**Range**	**Mean**	**SD**	**95% CI**
Outer circumference at the colonic end (cm)	9.5-15.5	11.86	1.60	11.2-12.5
Outer circumference at the rectal end (cm)	11-18	14.03	1.83	13.3-14.7
Difference of rectal and colonic circumferences (cm)	1-5	2.17	1.11	1.7-2.6
Time required for anastomosis (min)	38.3-63.5	47.7	6.92	44.9-50.5
Outer circumference of the anastomosis (cm)	8-14.5	10.88	1.55	10.3-11.5
Acute pneumatic leak pressure (mbar)	23-140	54.51	24.85	44.5-64.6

The pattern of acute pneumatic leak pressure is shown graphically in the graph 1.

Graph 1.



Graph1. The distribution of the acute pneumatic leak pressure. Yellow line =anastomotic leak pressure, green line = mean leak pressure.

There was no anastomotic stenosis; however there was 8.3% reduction in the average outer circumference of the anastomosis from that of the colon. Overall there were 8 spots (in the area of a single stitch) with visible mucosa along the anastomotic line and this was seen in seven anastomoses (Figure 76).

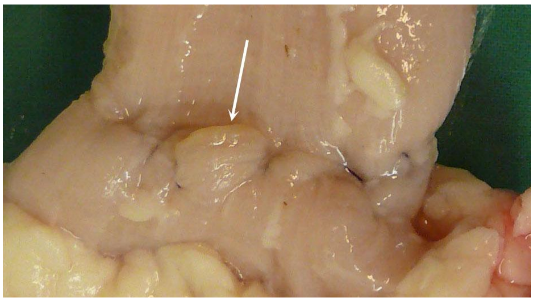


Figure 76. Mucosal eversion

Serosal defect (area where serosa to serosa apposition was not there but without mucosal eversion) was seen in seven spots in four anastomoses. Altogether, eleven anastomoses had either mucosal eversion or serosal defect. (One anastomosis had three spots, two anastomoses had two spots and eight anastomoses had one spot). Total numbers of stitches placed were 779 and in 15 spots (1.92%), it was not possible to have a serosa to serosa apposition

Quality of stitch placement is summarized on the table 5.

Table 5

Variables	**N**
Anastomosis	26
Total suture placed	779
Spots with visible mucosa	8 (1.03%)
Spots with serosal defect but without mucosal eversion	7 (0.89%)
Sutures with serosa to serosa apposition	764 (98.07%

We considered anastomotic leakage if the acute pneumatic leak pressure was below 25 mbar. Only one anastomosis had leakage by this standard. In this particular anastomosis, there was mucosal eversion in one place and the leak occurred through this site. Although, there was mucosal eversion in another seven cases, none of them had air leak through this everted site during the acute pneumatic leak test. Figure 77 shows leakage of air (air bubbles) at very high pressure.

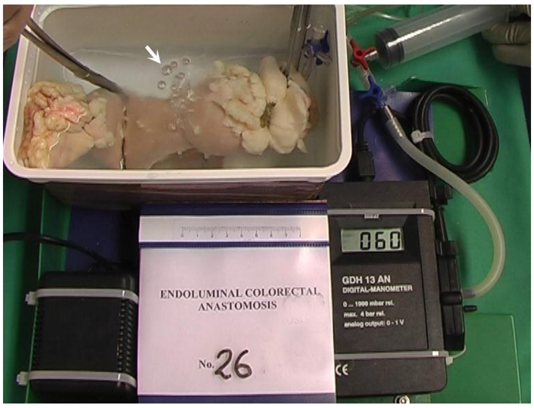


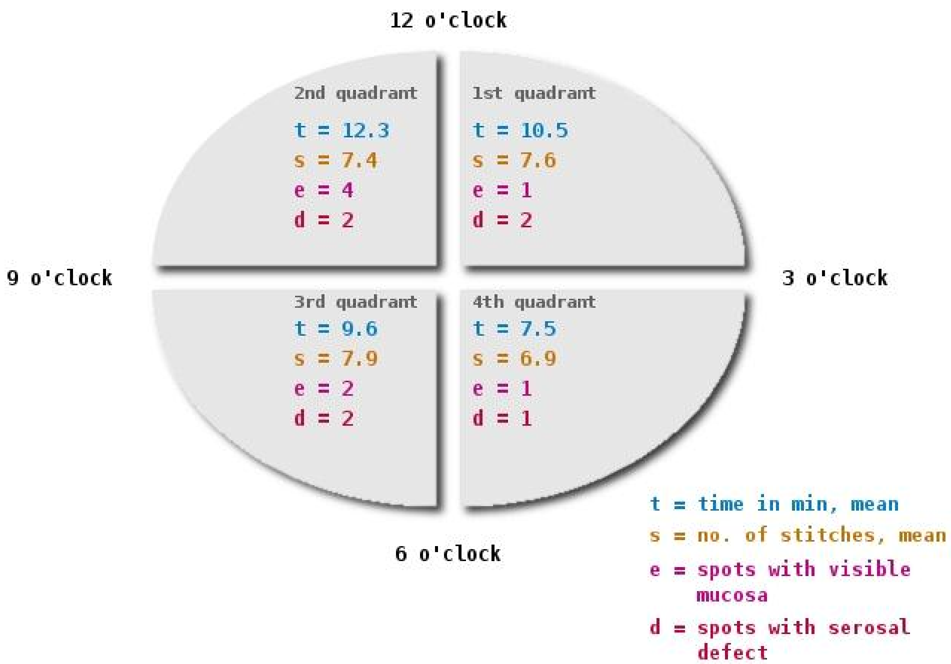
Figure 77. Leakage of air through the anastomosis (Air bubbles)

The distributions of operation time, number of stitches and the errors in stitch placement in the four quadrants of the anastomosis are shown in table 6 and graphically shown on graph 2.

Table 6.

Variables	1st quadrant (12-3 o' clock)		2nd quadrant (9-12o' clock)		3rd quadrant (6-9 o' clock)		4th quadrant (3-6 o' clock)		P value
	Range	Mean	Range	Mean	Range	Mean	Range	Mean	
Time in min	6.4-16.9	10.5	6-19.4	12.3	4.9-13.6	9.6	4.8-16-8	7.5	<0.0001
No. of stitches	5-12	7.6	6-9	7.4	6-13	7.9	5-9	6.9	>0.0723
Spots with visible mucosa	1		4		2		1		>0.4743
Spots with serosal defect but without mucosal eversion	2		2		2		1		>0.3526

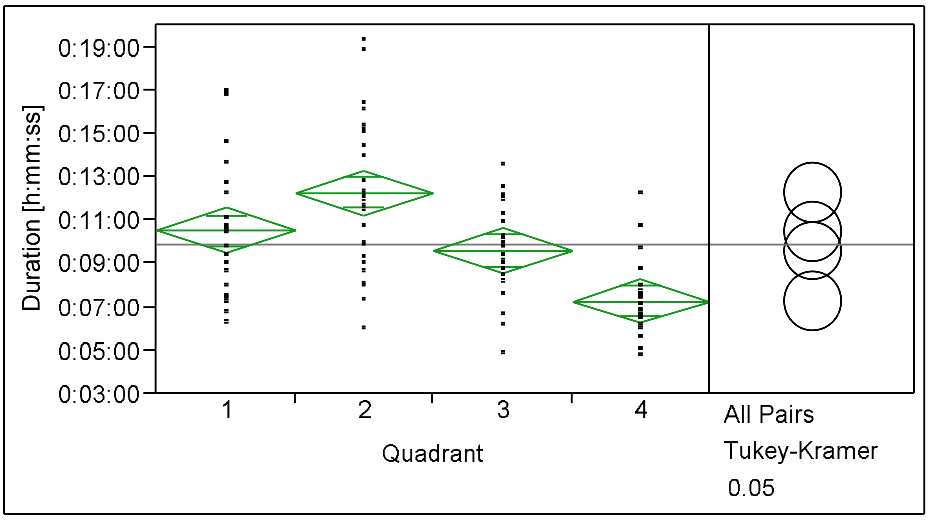
Graph 2.



Graph2. The distribution of time, stitches, spots with visible mucosa and serosal defect among the four quadrants of the anastomosis

The 2nd quadrant (9 to 12 o' clock position) took more time than the other quadrants which is statistically relevant against 3&4th quadrant ($p<0.0001$, One way ANOVA, Tukey-Kramer test) and was more difficult. The difference in operating time is shown graph 3.

Graph 3



Graph 3. Distribution of time among the different quadrants of the anastomosis

Although, did not receive statistical significance, this quadrant also had more difficulty in apposing the serosal layers of the colon and rectal walls (6 out of 15 spots).The anterior hemi circumference took more time and was difficult for serosal apposition of the rectal and colonic wall compared to the same on posterior hemi circumference.

3.4. Endolumenal stapled colo-rectal anastomosis

Twenty stapled endolumenal colo rectal anastomoses were performed with 25mm re-useable circular stapler. Figure 78 and 79 shows the external view of the stapled anastomosis.

Figure 78. The external view of stapled colorectal anastomosis (Anterior wall)

Figure 79. The external view of stapled colo rectal anastomosis (Posterior wall)

The main outcomes are summarized in the table 7.

Table 7

Variable	Range	Mean	SD	95% CI
Outer circumference at the colonic end (cm)	8-10.5	9	0.67	8.7-9.3
Outer circumference at the rectal end (cm)	10.5-13	11.6	0.78	11.2-11.9
Difference of rectal and colonic circumferences (cm)	1-4	2.57	0.89	2.15-2.99
Time required for anastomosis (min)	35.3-66.3	44.3	7.06	41.1-47.6
Acute pneumatic leak pressure (mbar)	12-68	37.2	10.95	32.0-42.2

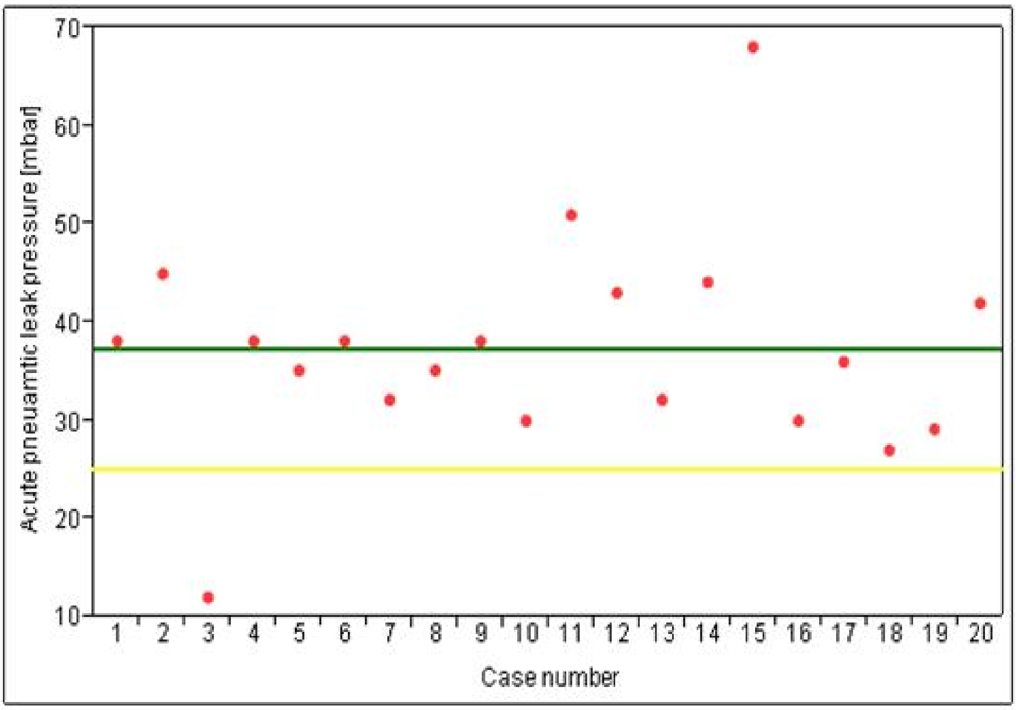
The operative time required during the different steps of the staple anastomosis is shown in the following table 8.

Table 8

Variables	**Range (min)**	**Mean (min)**	**SD**	**95% CI**
Purse string suture on the colon	5.3-15.5	8.1	2.26	7.0-9.2
Securing the anvil	3.8-15.4	8.1	3.25	6.5-9.6
Purse string suture on the rectum	9.7-26.9	17.5	4.14	15.5-19.4
Securing the rectal wall on the anvil post	3.5-18	6.7	3.29	5.1-8.2
Mating the anvil with stapler and anastomosis	1-6.4	3.9	1.45	3.2-4.6
Total	35.3-66.3	44.3	7.06	41-47.6

The pattern of acute pneumatic leak pressure is shown graphically in the graph 4.

Graph 4



Graph 4. The distribution of the acute pneumatic leak pressure. Yellow line =anastomotic leak pressure, green line = mean leak pressure.

The insertion of the anvil to the colon was straight forward in fourteen cases. In six cases more than two attempts were needed to insert the anvil. There was no eversion of mucosal or muscular layer of either colon or the rectum and the serosa to serosa was apposed in the entire circumference of the anastomosis in all the cases.

Two doughnuts were incomplete, one on the colonic tissue and one on the rectal tissue. However, none of these two procedures had anastomotic leakage (Figure 80).

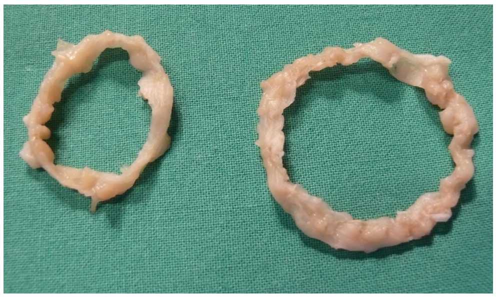


Figure 80. The complete doughnuts

There was one leakage close to the anastomosis. This leak was not along the line of anastomosis but through a small hole on the rectal wall close to the anastomosis. The hole was not perceptible during regular inspection of the anastomosis before the leak test and the doughnuts were also complete. The video of the procedure was reviewed. The injury was probably caused by the grasping forceps while pulling the thread after completing the purse string suture on the rectum. This happened in the early phase in the experiments. In the subsequent cases, this type of injury could be avoided by carefully pulling the thread and keeping the supporting instruments away form the rectal wall.

3.5. Comparison between stapled and hand sutured anastomosis

The comparative results between the hand sutured and the stapled anastomotic groups are summarized in the table 9.

Table 9

Variables	Hand sutured anastomosis, n=26	Stapled anastomosis, n=20	P value
Outer circumference of colon, mean in cm, (SD)	11.86 (1.60)	9 (0.67)	<0.0001
Outer circumference of the rectum, mean in cm (SD)	14.03 (1.83)	11.6, (0.78)	<0.0001
Operation time, mean in min (SD)	47.7 (6.92)	44.3 (7.06)	>0.0727
Anastomotic leak	1	1	>0.8558

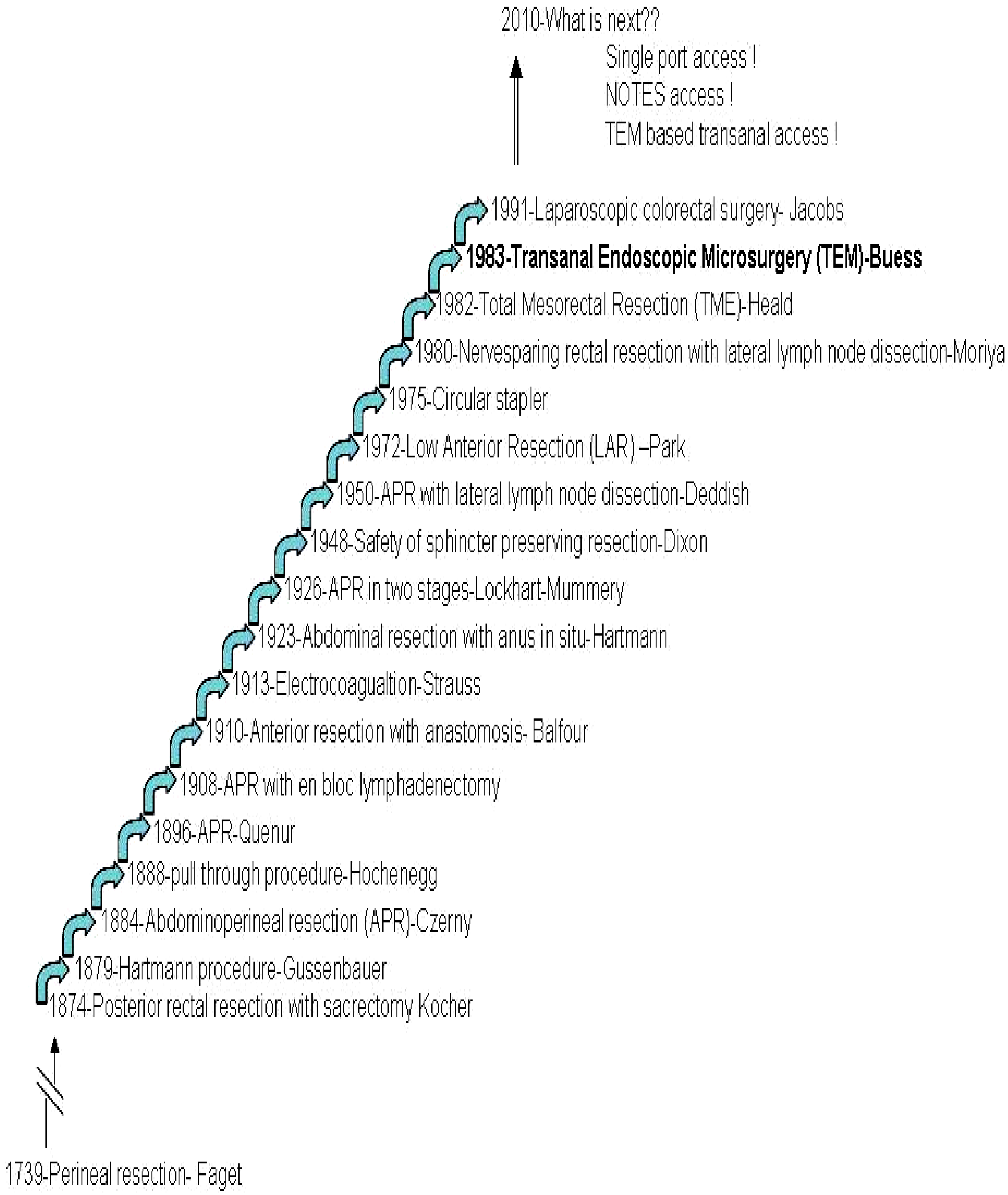
The differences in circumference of the rectum and the colon in both the anastomotic techniques were significant ($p<0.0001$, t Test, Wilcoxon Test). However the operation time and the anastomotic leak rate were similar in both the groups.

4. Discussions

4.1. Evolution of colorectal surgery

Surgical treatment of colorectal diseases is in constant evolution. This evolution process is filled with examples of great insight, vision and careful study to achieve better outcome and patients' satisfaction. There have been several paradigm shifts in the philosophy of management for colorectal diseases, incorporating large numbers of surgical approaches and resection techniques. The surgical technique followed and the quality of resection performed dictates to a large extent the oncological outcome and quality of life following colorectal surgery. Over time, techniques like perineal and sacral resection, abdominal resection (Hartmann procedure), abdominoperineal resection (APR), sphincter preservation (Anterior resection, AR), total mesorectal resection (TME), nerve preserving resection, endolumenal resection (Transanal Endoscopic Microsurgery, TEM), laparoscopic resection have emerged in the field. Some of these techniques waned off, some stayed on and some are still evolving. However, it is human nature to seek the best, hence, the exploration for a better technique to ensure better outcome in patients goes on.

With the accumulating knowledge on the biological behaviour of cancer and cancer spread, the local and distant failure rate following colorectal surgery is reasonably acceptable. Besides the fairly acceptable and reproducible oncological outcome, the focus goes now to the question of quality of life following surgery. Concerns for sphincter functions, sexual functions, urological functions, post operative wound related complications and by all these the overall quality of life have gained much interest. TEM and laparoscopy have revolutionized the post operative recovery and patients' satisfaction; however, there are still some areas to be further looked upon. Probably, it is high time to think beyond the frontiers of laparoscopic colorectal surgery. Concepts like single port access, NOTES access and TEM based transanal access have already knocked our door. The important developments which have influenced the evolution of colorectal surgery are highlighted in the following graph (Graph 5).



Graph 5. Important developments in colorectal surgery

Abdominoperineal resection described by William Ernest Miles in 1908 was the first rectal procedure based on the anatomical and biological principle of cancer spread. He considered that cancer spread, particularly in lymphatics, occurs in all directions ("cylindrical concept") and the involved lymph nodes are responsible for local recurrence of the disease. Consequently he removed the rectum with the associated lymph nodes en-block (73). In 1923, Miles reported a local recurrence rate of 29.5%. This was a path breaking result and the principles of the procedure are still applied nearly as 100 years ago. APR succeeded in lowering the recurrence rate following rectal cancer surgery, but it is a mutilating operation, needs permanent stoma and is associated with urogenital dysfunction; so a less mutilating operation was always in search. In 1948, Claude Dixon reported the first successful large series of sphincter preservation surgery for rectal cancers with a mortality of 2.6 percent and a five year survival of 64 percent (33). Subsequently, the better understanding on adequate distal margin and the development of circular stapler technology initiated a historical shift of radical APR to sphincter saving technique like anterior resection (AR) in the late 1970.s. However, the dissection techniques were blunt and were associated with high positive lateral margins. This culminated in a new technique of sharp dissection in the embryologically defined surgical planes (total mesorectal excision, TME) by Heald. The technique of TME resulted in significant decrease in positive lateral margins, reduced per operative blood loss due to sharp dissection, provided a reproducible specimen for pathological examination and reduced the local recurrence rate significantly (from 12-20 percent to 4 percent) and soon became the gold standard for rectal cancer surgery (40).

These radical surgeries, either APR or AR, are highly invasive and are associated with considerable morbidities to the patients. To minimize these morbidities Buess brought in a new concept for management of early rectal tumours in 1983, a concept of local excision under endoscopic vision, the transanal endoscopic microsurgery (TEM). TEM by virtue of magnified stereoscopic vision, dedicated instruments and precise dissection technique became the standard of care for local excision of rectal adenoma and selective early rectal caners, and with similar oncological outcomes and minimal morbidities (3,6,8,32,39,41,62,82,84,91,103). Jacob reported laparoscopic colorectal surgery in 1991, since then, it has gained steady momentum. Laparoscopy, by virtue of improved and magnified vision, less tissue trauma has changed several aspects of colorectal surgery. Integration of new and better technology for haemostatic dissection has made laparoscopy almost blood less. In contrast to the ‘touch guided’ open approach, laparoscopy for rectal cancer offers a meticulous and easy dissection of the mesorectum under direct vision. Worldwide literature consistently demonstrates the short term benefits of laparoscopic colorectal surgery over open colorectal surgery (77,78,96).The long term outcomes also suggest similar disease free survival, overall survival, local recurrence and quality of life after open or laparoscopic colorectal resection. Although, the rate of positive circumferential margin was more in laparoscopic anterior resection group, however, it did not influence the long term outcome (49). Today, these minimal access techniques are the preferred option for colorectal resection.

4.2. Limitations of present minimal access techniques

TEM and laparoscopic colorectal surgery have lessened to a large extent the post operative morbidities following colorectal surgeries. However, TEM is recommended only to a small group of highly selected patients. Laparoscopic colorectal surgery although minimizes the length of incision but it still requires a minilaparotomy for specimen removal and multiple incisions on the abdominal wall for port placement, which are source of post operative discomfort and incisional hernia (4).

Laparoscopy also has indigenous basic problems which are compounded by the loss of tactile feedback. Due to the width and the limited reticulation of the stapling devices, intracorporeal division of the rectum is technically difficult and becomes cumbersome when confronted with narrow and elongated pelvis (16). Often the rectal division is more oblique rather than transverse requiring more numbers of linear stapler firings. More than two linear stapler firings used during the rectal division and the crutch of the stapler are known risk factors for the anastomotic leakage. (44,55,60). The present staple technology has made deep pelvic anastomosis easier, but due to the width of the instruments a considerable length of the rectum needs to be dissected free below the resection line for placement of the clamp. This might influence the perfusion of the anastomosed tissue making it vulnerable to anastomotic leakage. Due to the loss of tactile feedback and absence of endolumenal vision, the tumour localization and precise determination of safety margin is often difficult in laparoscpopic surgery. This is more so when confronted with low rectal lesions or with flat early tumours.

4.3. The future

The future of colorectal surgery is directed towards better patient safety and outcome. The future technical development should address issues like

1. The trauma to the abdominal wall incurred during the mini-laparotomy for the specimen removal and multiple incisions for port placement.
2. Better view of the endolumenal aspect for clear identification of the safety margin.
3. Better view of the operating field for the safety of the nerve plexus and meticulous mesorectal resection.
4. The solution of the technical difficulties for division of the rectum and subsequent anastomosis deep in the pelvis.

4.4. Fundamental basis for the development of transanal rectosigmoid resection technique

Transanal Endoscopic Microsurgery (TEM) is the first endoscopic operation performed in the area of visceral surgery and the development of the TEM technology was started in 1980 (19). We have now almost three decades' long clinical experience on TEM. TEM offers markedly improved optics with stereoscopic view, better illumination, camera stability and spatial orientation (due to the gas insufflations and working in a distended lumen) compared to the flexible endoscopy. The rigid and robust instruments of TEM offer the operator more precision, better tactile feedback and bimanual operating abilities. The dedicated functional device for specific surgical task can allow haemostatic dissection when ultrasonic scissors are used. TEM was intended for local excision of tumours but in the course of clinical events mainly on full thickness excision of the tumour, we have gone beyond the rectal lumen and entered the peritoneal cavity on several occasions. Entry into the peritoneal cavity during TEM does not increases the post operative infective or oncological consequences (7,37). We had experience of removing perirectal fat with upto four lymph nodes, complete segmental excision of rectum with end to endo anastomosis way back in 1988 (21). The view of pelvis during these extra rectal dissections was highly impressive and helped in the meticulous and précise dissection. Our clinical experiences as well as the world wide literature concerning TEM made us to hypothesize that transanal colorectal surgery has the potential to be the next step in the evolution of colorectal surgery. Today, we believe that the existing clinical problems and theoretical aspects could be partly or even totally prevented by the new principle of transanal access.

4.5. The technical details of transanal rectosigmoid resection

The present technique for transanal rectosigmoid resection has incorporated several modifications to the standard recto-sigmoid resection. The predominant features unique to this technique and their pros and cons can be briefed as follows:

1. Endolumenal view and prevention of spillage: The rectal lumen is closed with an endolumenal purse string suture. This closure of rectal lumen helps to avoid the ongoing contamination from the proximal colon and also the possible tumour cell seedlings. The tampon makes the closure tighter. In case of clinical trials, the endolumenal visualization of the tumour will help in precise determination of the safety margin. The tampon could be soaked in bactericidal solution and rectal stump would be washed copiously before dividing the wall in order to minimize the contamination of the peritoneal cavity (Bacteria and tumour cells).

2. Better view in the pelvis: The rectal wall is divided from inside and dissection of mesorectal tissue is carried out in retrograde fashion. The divided rectal stump is grasped with the forceps and pushed away from the operating field providing adequate traction on the dissection site. As the dissection proceeds, the resected rectal stump is pushed towards the peritoneal cavity. This produces a clear unobstructed “empty pelvis” view of the operating field (Figure

45,46). Dissection in the pelvis specially when confronted with a narrow pelvis is always a challenge for the colo-rectal surgeon. Laparoscopy had changed the conventional “touch guided” open dissection technique for mesorectal resection to a more meticulous vision oriented technique. We believe this “empty pelvis” view coupled with the stereoscopic image from the TEM optic would enhance the safety of mesorectal dissection further in the transanal technique.

3. No additional viscotomy: A major possible advantage of our technique is the use of the transection site of the rectal wall as the definitive site for colo-rectal anastomosis, thereby obviating the need for an additional viscotomy closure.

4. Control of the vessels: The long curved instruments facilitate the dissection and division of the inferior mesenteric artery at its root. In two operations the applications of clips on the vessels were cumbersome. It was due to the straight clip applicator, which needs to be aligned by moving the whole system to clip the vessels. The movements of the system need to be very cautious as it also move the grasper holding the artery. In future, development of a curved rotatable clip applicator will solve this problem. Another interesting aspect is that, only today, during this step in the entire procedure i.e to guide the recto-scope during clipping of the vessels, the operating surgeon needs an active help from an assistant.

5. Preparation for anastomosis: Bringing down the colon to the pelvis after the mobilization facilitates preparation of the anastomosis under the better vision of TEM optics. It also ensures that the colon is adequately mobilized for a tension free colo rectal anastomosis in the pelvis.

6. Specimen delivery: We performed the proximal transection of the colon after mobilization to the pelvis and deliver the en bloc specimen through the recto-scope. Transanal specimen delivery, although attempted quite early in the evo-lution of laparoscopic colorectal surgery (30), upto now did not receive wide acceptance. Presently, it has regained interest and several authors have shown feasibility and efficacy of transanal specimen delivery after colo rectal resection (2,26,79). Whiteford et al and Sylla et al. in their investigational study on

transanal recto sigmoid resections delivered the specimen through the anus, divided the colon extra corporeally and inserted the stapler anvil to the colon in a regular way outside the anus (93,102).

Bringing the colon completely out of pelvis for transaction bears the risk of excessive traction on the arch of Rioland. Incidences of intra abdominal bleeding due to the rupture of the arc of Rioland are reported following transvaginal delivery of specimen after laparoscopic colorectal resection (97). By intracorporeal division of the colon close to the rectal stump in the pelvis we could avoid the undue traction on the vessels, possible reduction of perfusion due to traction as well as ensure the optimal colonic mobilization for a tension free anastomosis.

7. Peritoneal contamination: One big concern is that we have opened colonic lumen just before the anastomosis. Application of a detachable bowel clamp as shown in a subset of experiments would limit the contamination. However, the application of detachable clamp would be possible only in stapled anastomosis but not in the hand sutured anastomosis. In future, probably development of an inflatable intralumenal balloon which could be placed inside the colon to limit the contamination would solve the issue for both types of anastomoses. Clinical experiences with TEM over decades show, that the bowel can be cleaned with preoperative and intra operative measures, so that passage of stool can be prevented.

8. Insertion of the anvil: The insertion and fixation of the stapler anvil to the colon were made intra corporeally and was carried out in two steps. First, a purse string suture was placed on the edge of the colonic stump and then the anvil was inserted and secured to it by multiple sliding knots. In the later step, stabilization of the colon was crucial and was largely facilitated by the curved design of the anvil introducer (Figure 65). The anvil was first partly introduced into the colon, it then pressed the posterior colonic wall against the pelvis and stabilized the colon. The instrument on the right hand then glided the rest of the colonic wall over the anvil. This systematic way makes the task easier and was straightforward in 70% of the procedure. Difficulty was encountered during early

phase of the experiments and in smaller diameter of the colonic lumen. These two steps could be accomplished in a reasonable operating time (Table 8).

9. Joining of the anvil post to the stapler: During the final stage of the stapled anastomosis, the purse string suture on the rectal edge is tied on the anvil post and trocar of the circular stapler is mated to the anvil post under endoscopic vision. The thread tied to the anvil post plays a crucial role during this phase. It behaves like a handle to bring down the colon near to the rectal stump and stabilizes the anvil post while the rectal purse string is being tied. It then helps in joining the anvil post to the trocar of the circular stapler and transmits the traction and counter traction force required to fix the anvil to the stapler. It is important that the thread is brought out through the lumen of the anvil post, otherwise while pulling the thread the anvil rotates and takes an oblique position. In this position, it becomes extremely difficult to complete the mating process of the anvil post with the stapler (Figure 64). The present existing details related to the work with simple technical solution, will be optimized before clinical application by a second generation of specific instruments.

10. Prevention of anastomotic stenosis: In the hand sutured anastomosis, the anastomosis is performed in four quadrants. This division of the entire anastomotic circumference into four segments minimizes the possibility of anastomotic stricture.

11. Managing the difference in lumenal size: The posterior hemicircumefernce of the anastomosis is performed after the completion of the anterior hemicircumference. This has an important technical implication. TEM suturing is technically easier on the posterior hemicircumference than on the anterior. After completing the anastomosis on one hemicircumference, the discrepancy in lumenal size between the rectum and the colon is more marked and appreciable. So, by virtue of technical ease and well planned geometric stitches, the diameter difference is handled better on the posterior hemicircumference.

12. Stay suture: Another technical modification in the hand sutured anastomosis is the placement of the inverted U shaped stay suture at 6 o' clock postion. This stay suture fulfills two important objectives. Firstly, it approximates the midpoints of posterior hemi circumference of the rectum and that of the colon. Thus, it distributes the remaining differences in lumen size equally between the third and fourth quadrants of the anastomosis. Secondly, the specific shape of the stay suture (inverted U) approximates the serosa of both the rectal and colonic wall at the centre of the hemi circumference and arranges them in parallel position to each other (Figure 59, 60). This parallel position of the bowel walls facilitates serosal apposition and optimal placement of the sutures.

4.6. Comparison of TEM based NOTES in literature with other experimental activities for colorectal resection

Natural Orifices Translumenal Endoscopic Surgery (NOTES) is been projected as the next surgical revolution. The feasibility of NOTES in preclinical and basic clinical settings has already been established (13, 35, 47, 48, 50, 51, 52, 53, 71, 72, 83, 95,100, 104,105). However, for the progress and expansion of this new domain, it is important to investigate the applicability of NOTES, not only in diagnostic or minor surgical interventions but also for major surgical procedures like colorectal resection. The difficulties with flexible endoscope in surgical dissections, organ retractions and safe closure of a viscerotomy are well recognized (5, 89). Presently there are three published reports of NOTES colorectal resection. One publication is purely based on TEM, one with TEM and flexible endoscope and the other one is purely based on flexible endoscope (63, 93, 102). Leroy et al. in their purely flexible endoscope based technique used a double channel gastroscope for sigmoid resection in swine model. The dissections were performed with regular endoscopic instruments. They divide the colon by a linear stapler introduced to the peritoneal cavity through transrectally placed trocar. For retracting the sigmoid colon they used a transanally placed rigid manipulator (63). However, this type of retraction is technically feasible only in animal model due to the midline and straight alignment of rectum and sigmoid colon. Feasibility of retracting sigmoid colon in human by a transanally placed rigid manipulator is questionable. Development of new technologies can only solve these difficulties associated with flexible endoscope. TEM, on the contrary, is in clinical practice for nearly three decades. Its instruments are rigid and robust for a large organ retraction and are designed for bimanual surgical tasks. Applicability of TEM as portal for NOTES has been evaluated by several authors (93,102). TEM offers markedly improved optics with stereoscopic view, better illumination, camera stability and special orientation compared to the flexible endoscope. The rigid and robust instruments of TEM offer the operator more precision, tactile feedback and bimanual operating abilities. Whiteford et al investigated the applicability of TEM for sigmoid resection. They performed radical sigmoid resection in three human cadavers using the TEM system (102). However, due to the short instrument length their cephalad mobilisation was limited to the descending colon and they could reach upto the proximal superior haemorrhoidal artery. Sylla et al. tried to overcome this limitation of instrument length by using transgastric endoscopic assistance (93). Although, in a subset of their animal experiments, they succeeded to mobilize more length of descending colon by using endoscopic assistance, but the deliberate gastrostomy for the endoscopic assistance is always an added risk.

4.7. Our TEM based principles compared and validated to other developments

In our study, we could demonstrate the feasibility of transanal rectosigmoid resection and colorectal anastomosis in an ex vivo experimental model with the TEM technology. The new sets of long instruments helped us to overcome the limitation of instrument length as encountered by the previous investigators. Most of the dissections could be performed with existing TEM system (Table 3); the added advantages of the new long steerable instruments were to divide the inferior mesenteric vessels at its root and to mobilize the descending colon up to the splenic flexure. The curve and the rotatable design of these instruments allowed accessing a larger working field even after passing through a single port (Figure 29). Due to the length of the instruments and close working space, there are conflicts between the instruments or between the instruments and optic. However, these conflicts are common in single port surgery and did not hinder safe performance of the procedure. The established principles of laparoscopic colorectal surgery like adequate exposure, traction and counter traction at the operative site, precision of dissections could be reproduced and a significantly long specimen (mean length 37.2cm) is delivered safely through the transanal route.

In the hand sutured anastomosis, there were fifteen spots (area of a single stitch) where serosa to serosa apposition was not possible. Of these, only one had significant leak. It can be *stated* that although there was lack of serosas to serosa apposition, the bowel walls were well apposed in these areas and the eversions were very small. The difference of lumenal circumference between the rectum and the colon varied from 1-5cm (mean 2.17)). These suggest that in actual clinical situation, negotiation with the luminal discrepancy, which is a fairly common occurrence, will not be a difficult issue in this endolumenal technique.

The second quadrant (9 to 12 o’ clock position) in the anastomotic circumference is technically difficult as represented by the longer operative time and number of spots with mucosal eversions than the other segments of the anastomosis. Thus, during the training and clinical application of the technique, surgeons need to be more careful in this segment of the anastomosis.

Air leak test is a common clinical practice to check the integrity of the anastomosis and is helpful in minimizing the anastomotic leakage following colorectal anastomosis (10,38,86). This test is usually subjective as one cannot go on increasing the pressure until the anastomosis actually leaks. In our studies we considered an intralumenal pressure of 25 mbar as the cut off margin and any leakage occurring below this level is considered as anastomotic leakage. This deduction is partly based on the work of Gilbert et al (38). They recommended raising the intralumenal pressure upto 25 cm of saline for the leak test as all the anastomotic leakages in their series occurred at a pressure below this level. There was one significant anastomotic leakage on both hand sewn and stapled anastomoses group. These leakages were seen during the early phase of the study and can be attributed to learning curve effect.

Difficulty of rectal transection especially in a set up of low rectal resection is well recognized in laparoscopic colorectal surgery. Due to the present limitations of linear staplers, the staple line is often oblique and long and the uses of more than two linear stapler firings are associated with increased risk of dehiscence. (44,55)The crutch of the staple is also associated as a risk factor for anastomotic leakage following colorectal anastomosis (60). In the present technique of circular staple anastomosis, the problems related to staple line intersection, difficulty in use of linear stapler, crutch of the staple line could well be avoided. However, the safety and efficacy of this technique can only be commented after survival studies.

Due to the significant difference in the rectal and the colonic circumferences in hand sutured and stapled anastomoses, a head on comparison between the two techniques is difficult in terms of operating time. The safety of anastomosis in terms of anastomotic leakage is comparable in both the techniques. 15 spots in eleven hand sutured anastomoses did not have serosa to serosa apposition; however, the clinical significance of such small failures needs further study.

4.8. The advantages of the transanal access

1. Endolumenal demarcation of the safety margin: The transanal access being an endolumenal technique has the direct view of the tumour and the safety margin could be defined safely and very precisely. In contrast, due to the lack of tactile sensation, it is often difficult to locate the tumour from outside and define the safety margin during laparoscopic colorectal surgery especially with early cancers or with flat tumours.

2. Better view into the pelvis: As the rectum is transected and retracted upward, the pelvis becomes empty. This unobstructed empty pelvis view coupled with the 3D vision of TEM optic would facilitate the safe and complete mesorectal dissection. Visualization and preservation of the autonomic nerve plexus and superior hypogastric nerve will be more easy and effective.

3. Lack of abdominal trauma: There will be no abdominal incisions either for removal of the specimen or for placing of the ports. This will not only have

cosmetic benefits but also have tremendous impact on post operative recovery. Lack of abdominal wall pain would definitely influence the psychological as well as the immunological aspect of patients' recovery. Abdominal incision is cosmetically undesirable and has its associated morbidities in the long run like risk of infections, scar, chronic pain, incisional hernia, etc. By completely avoiding the abdominal wall incisions, these sets of morbidities can be avoided in transanal access.

4. Endolumenal rectal division: The rectum is transected from inside and the line of division is perpendicular to the long axis of the rectum. Thus, the present limitations of rectal division in laparoscopic colorectal surgery like oblique and long transection line, crutch of staple line due to multiple firings could be avoided.

5. Perfusion of the rectal stump near the transection site: Due to the width of the clamp or the stapler, a significant length of rectum is mobilized beyond the transection line for placing the clamp or stapler blade in open or laparoscopic colorectal surgery. The mobilization of this extra length of rectum is likely to reduce the perfusion at the transection line and thus, jeopardizing the safety of anastomosis. In the present technique for staple anastomosis, the rectal stump is not mobilized further down the transection line and thus vascularity is not compromised at the site of anastomosis.

6. Solo surgery: With the emerging scarcity of trained manpower and increasing expense of operating staff, the concept of solo surgery is evolving. At the present moment, except clipping of the artery, the procedure can be performed without an assistant. With further development of a curve clip applicator, the artery could be clipped easily on a single surgery platform.

4.9. The disadvantages of the transanal access

1. TEM is a technically demanding procedure. The new long instruments are even more demanding and need considerable training and skills for their use.

2. In the transanal technique, the rectal lumen and the colonic lumen are opened inside the peritoneal cavity. The clinical experience of TEM has shown no major complication following entry into the peritoneal cavity, but compared to laparoscopic colorectal surgery, where complete asepsis is maintained during dissection, this will stay a disadvantage depending on the bowel preparation.
3. The large tumours or colon with very fatty mesocolon will not be possible to remove through the TEM tube, they may be either removed through the anus without the tube or may not be possible at all. Thus the indications of the technique will be limited to the smaller and middle size tumours.

4.10. Our experimental setup: a future training module

We performed the experiments in an experimental model with integrated animal organs collected from slaughter house. Due to the uniqueness of human pelvis, no animal could provide a realistic anatomy. We believe that the development of a surgical technique in a surrounding not related to human anatomical condition would preclude its dispersion to real clinical scenario. European Association of Endoscopic Surgery (EAES) guidelines for methodology of surgical innovation also suggest that for preclinical evaluation of new innovation, the simulation is to be performed in animal organs or organ blocks with similarity to human organs and integrated into human anatomical surroundings (76). For training of laparoscopic colorectal surgery in our institute, we are using the young bovine lower gastro intestinal organ block for more than ten years (101). In the present experimental set up, the calf colon is mobilized from midline by dividing some flimsy peritoneal attachments to bring it to lateral location like in human. Multiple sutures were used to simulate the peritoneal attachment and the normal adhesions of the human anatomy. Simulating by sutures, the position of the sigmoid colon, descending colon and splenic flexure are placed in a realistic platform for development of a surgical technique. Several visiting general and colo-rectal surgeons also validated this fact. The organs from the slaughter house are relatively cheap and easily available. So a large number of experiments could be performed with relatively few logistical hurdles. In the present experimental design, we performed more than one hundred experiments to develop and standardize the technique, then another fifty nine experiments to evaluate the technique. This large number of experiments would have never been possible if we were using live animals or human cadavers.

Any innovation is associated with the issue of training of the end users for safe dispersion of the technique. The unique features like easy availability, less expensive, realistic platform make the present experimental set up a promising training model for the coming days.

4.11. Limitations of the present study

There are some limitations to the study.

1. This is an ex-vivo analysis so results may vary in real life clinical situations.
2. Bleeding and effect from the surrounding organs were not simulated.
3. Although re integration into an anatomical trainer produce a realistic situation but it is not 100% reproduction of human anatomy.
4. The complete operation was performed in two set up.
5. The method for acute pneumatic leak test is very sensitive to detect even a minute leakage of air. This high sensitivity is probably necessary only for intralumenal pressure below 30mbar. When the intralumenal pressure is high, the tension on the thread applied for suturing or on the stapler pins also increases and eventually, they cut-through the wall and produce a “stitch channel” communicating the lumen to the exterior. Air leaking through these stitch channels although minute are picked up during the test and are responsible for most of the air leak occurring after 30mbar of intralumenal pressure. Probably, the cut-through effect is aggravated by the loss of tensile and elastic strength of the bowel during freezing and thawing process. So the importance of acute pneumatic leak pressure beyond 30mbar to evaluate the integrity of anastomosis is probably not relevant.

5. Conclusions

We have developed a technique for transanal rectosigmoid resection in an ex-vivo experimental model. We integrated the young bovine large bowel organ block to the Tuebingen MIC Trainer; the trainer being anatomical in design, this integration replicates human anatomy. The experiments were performed in this simulated environment. A new set of instruments have been developed for translumenal intraperitoneal work according to the principles of Transanal Endoscopic Microsurgery (TEM). These instruments are long, curved and steerable. The technique developed can be divided into the following steps: 1.Closure of the rectal lumen by an endolumenal purse string suture. 2. Transection of the rectal wall 1cm distal to the purse string suture and continuation of the dissection towards the fascia and upward excising the mesorectal tissue. 3. Inferior mesenteric vessel is dissected out and divided between clips. 4. The descending colon is mobilized along the white line of Toldt upto the splenic flexure. 5. The mobilized colon is then brought down to the pelvis. It is ligated twice at the proximal resection site and divided between the ligatures. 6. The specimen is delivered through the anus. 7. Intestinal continuity is restored by either stapled or hand sutured anastomosis. Most of dissections were performed with the regular TEM system while for control of the inferior mesenteric vessel and mobilization of the colon we used the new long instrument system. The experiments were performed in two setups. In the first setup, upper rectum and sigmoid colon were resected. In the second setup, the colorectal anastomosis was performed either by the hand sutured or the stapled technique.

Twelve colorectal resections were performed adhering to the existing principles of colo-rectal surgery. Mean operation time was 78.6min (SD=9.9). The average specimen length was 37.2cm. There was no injury to the resected specimen. During the dissection in the pelvis, as the specimen was retracted upward and toward the abdomen, an “empty pelvis” view of the working field was achieved. This facilitated the dissection. The mean operating time for the hand sutured anastomosis was 47.7 min (SD=6.9) and for stapled anastomosis it was 44.3

min (SD=7.1). There was one anastomotic leakage in both the groups. 98.07% of the sutures had serosa to serosa apposition in the hand sutured anastomosis. Doughnuts were complete in 18 out of twenty stapled anastomoses.

In conclusion, we would say, transanal recto sigmoid resection with colorectal anastomosis is feasible in experimental set up by the existing TEM technology coupled with the new modified instruments. The technique bears the promise of eliminating the morbidities related to the mini-laparotomy and incisions for multiple port placements during laparoscopic colorectal surgery. Meticulous and better dissection in the pelvis is anticipated due to the unobstructed "empty pelvis" view of the operating field. The technique is based on single port platform and almost the entire procedure can be performed by a single surgeon. Endolumenal colorectal anastomosis is feasible and safe for both stapled and hand sewn anastomosis and reproduces the existing safety principles of bowel anastomosis. The present experimental setup is a promising training module for the expected end users of the technique. However, to demonstrate the clinical safety and efficacy of the technique, we need further studies in clinical setup.

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Publications

Ten international publications