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Experimental Development in Colorectal Surgery

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A one year research programme on endoscopic colorectal resections was carried out at the University of Tübingen. Two research lines were planned: the development of the required technologies and the development of the surgical procedure. During the research programme on technologies a new device provided with an air proof system for transanal insertion of the anvil of a divisible stapler and a new technique for closure of the colonic and rectal stumps (cable binding technique) were developed. Such technological innovations enabled the authors to accomplish a new combined laparoscopic-rectoscopic procedure which was performed according to four different variants in a series of 32 animals. The last 15 consecutive successful cases, performed according to the definitive procedure, represented a standardized animal trial before starting the clinical investigation.

Introduction

There is a continuous increase of colorectal procedures in western countries due to the rise in the incidence of colorectal cancer and ageing related organ diseases. In the United States an estimated 12% of cancer deaths comes from colorectal malignancy and the incidence of colorectal cancer per 100,000 population is increasing at a rate of 0.7% per year (1–3). The management of patients whose postoperative course after colorectal open surgery was complicated was evaluated and found to account for 28% of the total costs in a recently reported series (1,4–6).

Among the most influential factors of the costs for management of colorectal diseases which could be involved in the development of new techniques or treatment strategies are the incidence of complications and the related length of the hospital stay (1).

To deal with cost-effectiveness and cost-benefit of a surgical treatment nowadays means also to talk about the postoperative quality of the patient's life and the patient's return to previous working or social activities. Looking at the advantages obtained with the laparoscopic approach to surgical treatment of different abdominal diseases (i. e. gallstones, oesophago-gastric junction disfunctions) in terms of cost containment, decrease in postoperative pain and hospital stay and improvement of the patient's quality of life (7–10), a research programme was planned at the University of Tübingen in order to develop a completely endoscopic procedure for colorectal resections. There are still several critical points and restrictions in minimal invasive surgery and these limitations are even more important when an endoscopic advanced procedure has to be performed (7,11). In all endoscopic surgical techniques and transanal endoscopic microsurgery (TEM) (12,13), stereoscopic vision is not possible and the image of the operating field is displayed by a television monitor, resulting in an alteration of the depth perception and problems with coordination. Because of the magnification provided by the viewing telescope, the identification or evaluation of anatomic structures is sometimes difficult; besides this, the lack of tactile sense during endoscopic surgery greatly reduces the surgeon's ability to discriminate between different tissues. Last but not least, the instruments' mobility is restricted due to their insertion through cannulae fixed to the abdominal wall. In order to overcome all these problems and set up a procedure that supports the aim of minimal invasive surgery, two parallel research lines were planned: 1. development of technologies; 2. clinical development. The technology programme was carried out by *Melzer, Roth* and *Reutebuch*, the surgical procedure was developed by *Buess* and *Lirici* and is characterized by a double endoscopic approach: laparoscopic and rectoscopic.

Material and methods

Development of technologies

The modified Buess operation rectoscope

Because of the narrow rectum of the mini-pig and medium-sized swine the Buess operating rectoscope (Richard Wolf GmbH, Knittlingen) (12,13) was provided with a 30 cm long tube with a 35 mm diameter, thus allowing surgical manoeuvres up to the distal sigmoid and an easy removal of the specimen (Figure **1**).

The slip-knot for monofilament suture materials

A new slip-knot especially designed for monofilament use, has been developed by *Melzer* and *Buess*. Figure **2** shows the steps of tying this double throw, double twist, double lock slip-knot. During colonic endoscopic surgery the Melzer-Buess knot is used not only for vessel ligatures but also for definition of the

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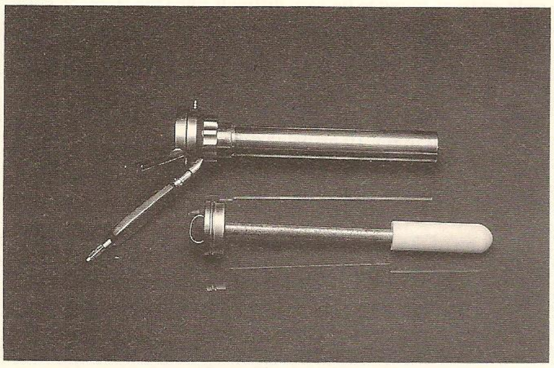

Figure 1: The Buess operating rectoscope provided with a modified un-bevelled tube 35 mm in diameter and 30 cm in length.

limits of resection by passing and tightening two PDS 0 (Polydioxanone, Ethicon GmbH, Hamburg, Norderstedt) threads around the bowel.

The anvil introducer and the anvil holder

The device, consisting of a double sheeted tube that allows the advance of the anvil inserted into the tip is provided with an 0-ring valve which exactly fits the lumen of the operating rectoscope (Figure **3**). The anvil introducer allows the transanal insertion of the anvil up to the proximal sigmoid in animal operations or to the descending colon in man, thus avoiding any leak of the pneumoperitoneum. The anvil holder is a special forceps designed for safe handling of the anvil while fixing it to the stapler's shaft (Figure **4**).

The cable-binding technique

An original technique that represents a real alternative to the time consuming purse-string suture has been developed and called "cable-binding technique". The "cable-binder" is a manufactured plastic device, provided at one edge with ratchets, which when tightened will not slip back (Figure **5**). Before use the cable-binder is pre-locked externally and inserted into a special pusher. At this moment the device is ready to be used like a conventional endo-loop.

Development of the surgical procedure

Choice of the animal model

During the research programme a number of procedures were needed in order to define the most suitable animal model. Three different animal models were tested in performing several operations according to the combined endoscopic procedure: mini-pig, sheep and medium-sized swine. In the first case the pelvis was too narrow and inhibited the proper handling of instruments and the passage of the operating rectoscope. In the second case the insertion of the laparoscopic cannulae at the

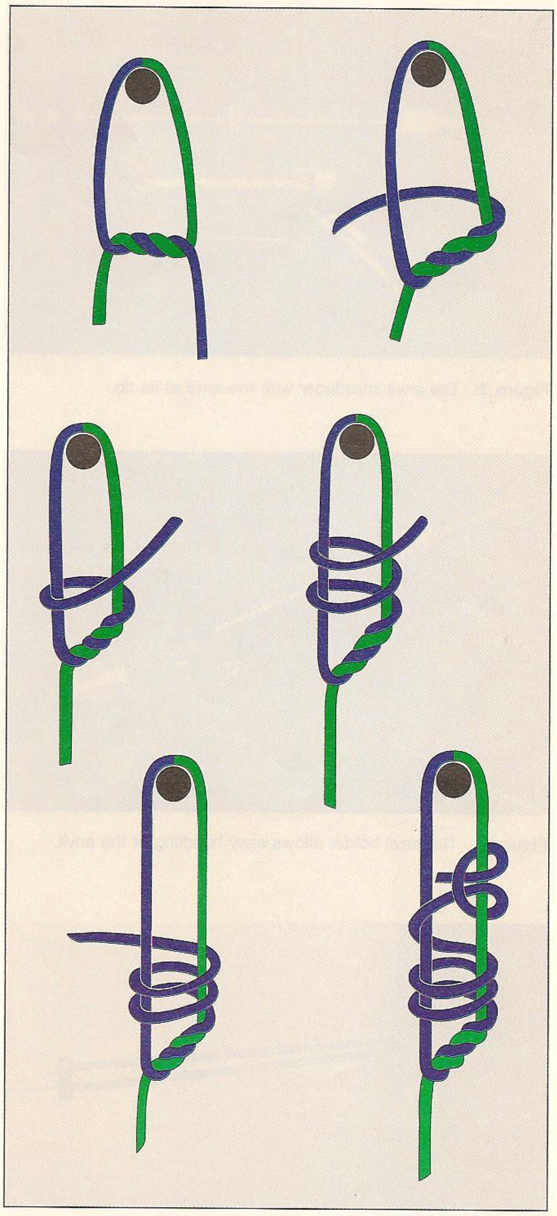

Figure 2: The five steps of preparing the Melzer-Buess external slip-knot: instead of Roeder's single throw and a single lock at the beginning and at the end, this knot starts with a double throw and is locked twice at the end.

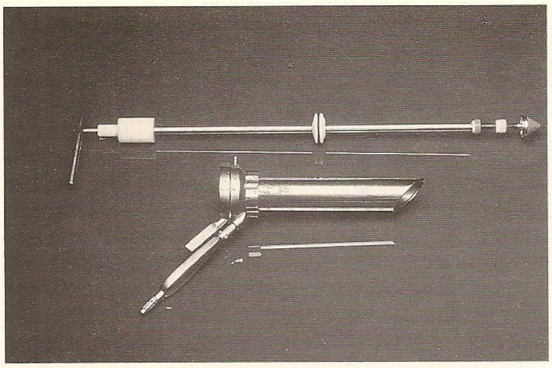

Figure 3: The anvil introducer with the anvil at its tip.

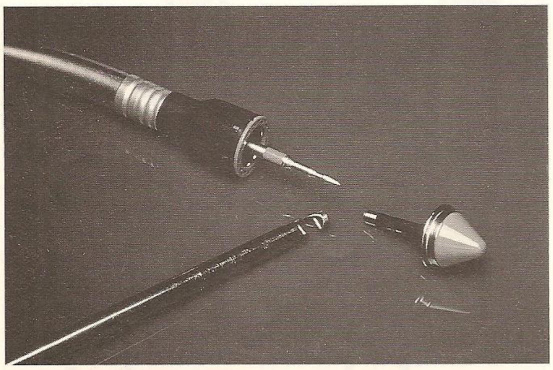

Figure 4: The anvil holder allows easy handling of the anvil.

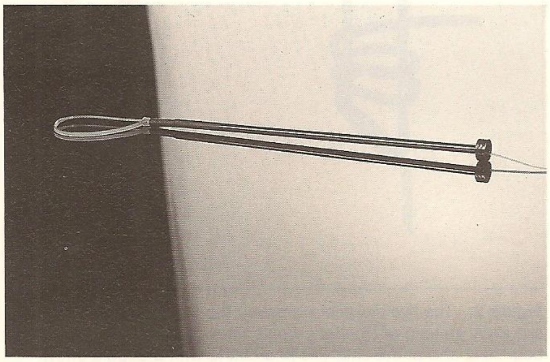

Figure 5: A prelocked cable-binder inserted into a special pusher: once tightened the ratchets at its end prevent it from slipping back.

right site was found to be very difficult since the stomach nearly entirely occupies the abdominal cavity: in most cases the surgeon had to work in the small space of the Douglas pouch. The medium-sized swine is definitely the most suitable animal model: no intraoperative problem related to the animal's anatomy occurred in the 16 swine operated on.

Surgical technique

The set-up of the surgical procedure required phantom tests and three operations in 1 mini-pig and 2 sheep at the beginning of the study. These three animals are not considered part of the experimental trial. An overall of 29 animals (6 mini-pigs, 7 sheep, 16 medium-sized swine) were operated on according to four different variants of the totally endoscopic sigmoidectomy. Such variants of the surgical technique were characterized by the application of different or new technologies. The last two techniques represent the endoluminal and extraluminal variant of the standardized procedure (14).

The preoperative protocol consisted of 3 days of fasting and enema. The animals were operated on under general anaesthesia with a central vein catheter and ECG monitoring. The postoperative protocol consisted of 1 to 2 days of fasting. Antibiotics were administered only if intraoperative complications occurred. On the third postoperative week the animals were put to sleep and the specimen including the anastomosis sent to the pathologist for microscopic evaluation.

- *Endoluminal procedure phase 1:* In this early phase the bowel stumps were closed around the anvil and the stapler shaft by a purse-string suture. A standard EEA straight stapler was used for the anastomosis.
- *Endoluminal procedure phase 2:* The cable-binding technique was performed instead of the purse-string suture. A modified, elongated, straight, circular stapler was used in order to reach the upper sigmoid more easily through the anus.
- *Endoluminal procedure phase 3:* This is the ultimate phase of such a variant, characterized by the application of the following technologies: "cable-binders", anvil introducer provided with an air-proof valve, use of a divisible, curved, circular stapler. The positioning of the surgical team, the positioning of the operative ports and the preparation of rectosigmoid are carried on as described for the extraluminal procedure. The anvil of an ILS 29 mm divisible stapler (Ethicon GmbH, Hamburg, Norderstedt) is inserted by means of the special introducer up to the proximal sigmoid. Two PDS 0 Melzer-Buess slip-knots are tightened around the bowel at its proximal and distal levels with the introducer inside. Afterwards, the anvil is fixed to the descending colon or to the proximal sigma by another external knot in PDS and the sigmoid is divided between the two proximal ligatures (Figure 6). A prelocked cable-binder is tightened around the proximal stump by means of the special pusher, thus reinforcing the PDS ligature and safely fixing the anvil. The proximal rectum is hence divided and the anvil introducer, with the specimen fixed around its rod, withdrawn through the rectoscope. Under laparoscopic control the rectoscope itself is re-

moved and replaced by the stapler shaft. As soon as the stapler shaft is seen on the monitor, its spike is advanced through the open rectal stump, held by a couple of graspers, and another prelocked cable-binder is tightened in order to close the stump around it. The colonic and rectal stumps are checked and exceeding tissue is resected. After insertion of the anvil, handled by the special anvil holder, into the stapler shaft, the stapler is closed, fired and carefully removed through the anus.

- *Extraluminal procedure:* The required technologies are similar to those of the standardized endoluminal procedure. The surgeon and the cameraman stand to the right and the assistant to the left of the table. After establishment of the pneumoperitoneum 4 cannulas are inserted in the lower abdomen. A 10 mm cannula is placed at the site to the right of the navel for the passage of a 50° telescope. An 11 mm cannula and a 5 mm silicon cannula are inserted in the lower right quadrant of the abdomen: the first is an operative port placed about 7 cm below and laterally of the navel, the second is an operative port required for the insertion of a curved grasper designed by *Cuschieri.* This port is placed close to the anterior iliac spine. Another 5 mm cannula is positioned in the left abdomen, opposite the 11 mm port. Under laparoscopic control a suprapubic puncture of the bladder is performed and a catheter left in situ. The operating table is then put in a mild Trendelenburg setting and turned to the right. The sigmoid colon is fixed to the abdominal wall by means of two rubber slings: this manoeuvre is accomplished by passing through the mesentery with the Cuschieri curved grasper and permits a clear view of the mesocolon and its vessels. The vessels to the sigmoid are freed and ligated by means of PDS 2-0 external slip-knots according to the Melzer-Buess technique and divided afterwards. Once the preparation of the sigmoid is accomplished, the modified Buess operating rectoscope is inserted into the rectum up to the recto-sigmoid junction. Two PDS 0 slip-knots are tightened around the sigmoid at its proximal and distal levels. The gas-proof anvil introducer loaded with the anvil of a 29 mm divisible stapler is inserted into the rectoscope and held in a stand-by position. Two small cuts are made, one on the upper rectum just below the distal ligature and one on the upper sigmoid just over the proximal ligature. The anvil is then advanced up to the proximal sigmoid, thus making the introducer pass through the two cuts (Figure **7**). The anvil is then fixed to the proximal sigmoid by tightening a PDS slip-knot, the introducer is withdrawn and the bowel divided by completing the upper cut. While the rectum is held with two graspers, the distal cut is completed. After division of the rectum, the specimen, grasped with a forceps passed through the rectoscope, is removed. A prelocked cable-binder is kept around the rectum: at this moment the rectoscope is replaced by the stapler shaft. After extrusion of the stapler's spike the cable-binder is tightened around the rectum. Another cable-binder is tightened around the proximal stump, thus reinforcing the previous ligature. After closure, the stapler is fired and the anastomosis checked by turning the 50° telescope and looking at both sides of the bowel and filling the rectum with 50 ml methylene blue solution (Figure **8**).

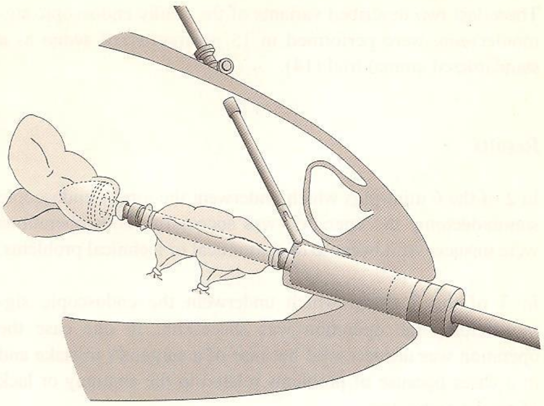

Figure 6: The insertion of the anvil during the endoluminal procedure. Afterwards the sigmoid colon will be divided between ligatures.

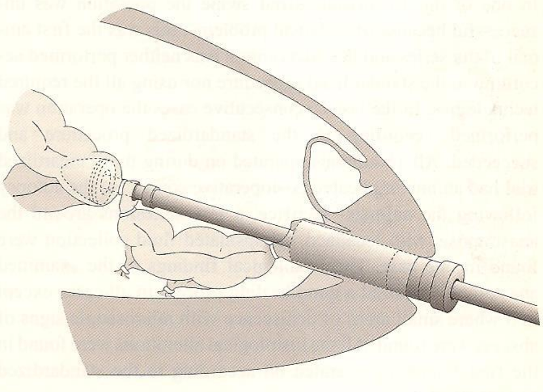

Figure 7: The insertion of the anvil up to the proximal sigmoid during the extraluminal procedure: the anvil introducer is advanced through the small cuts in the proximal rectum and proximal sigmoid colon.

Figure 8: Endoscopic view after completion of the anastomosis.

These last two described variants of the totally endoscopic sigmoidectomy were performed in 15 medium-sized swine as a standardized animal trial (14).

Results

In 2 of the 6 mini-pigs which underwent the totally endoscopic sigmoidectomy the operation was successful. Four operations were unsuccessful because of anatomical or technical problems.

In 3 of the 7 sheep which underwent the endoscopic sigmoidectomy the operation was successful. In one case the operation was unsuccessful because of a surgeon's mistake and in 3 cases because of problems related to the anatomy or lack of proper technology.

None of these animals were operated on according to the standardized procedure.

In one of the 16 medium-sized swine the operation was unsuccessful because of technical problems: this was the first animal of the series and the intervention was neither performed according to the standardized procedure nor using all the required technologies. In the last 15 consecutive cases the operation was performed according to the standardized procedure and succeeded. All 15 animals operated on during the standardized trial had an uncomplicated postoperative course. At the autopsy following the animals' sacrifice, a few adhesions around the anastomosis with localized, encapsulated fluid collection were found in one case. The histological findings of the examined anastomoses showed a good healing process in all cases except in 3 where small areas of dehiscence with microscopic signs of abscess were found. All the histological alterations were found in the first 5 animals operated on according to the standardized technique.

Discussion

The accomplishment of a completely endoscopic colorectal resection requires proper techniques for vessel ligatures, preparation of the bowel stumps and the intestinal anastomosis; besides this, technology is required in order to avoid gas leakage when the bowel is divided and for the specimen's retrieval (15).

Various ligature techniques are currently used in endoscopic surgery (11, 16). Because of its reliability and physical characteristics Polydioxanone (PDS) (Ethicon GmbH, Hamburg, Norderstedt) represented the first choice suturing material for vessel ligatures in our experiments. This monofilament is very strong and safe when tightened around a structure. It is very easy to slide down an external slip-knot in PDS, because the thread itself is slightly slippery. Polydioxanone does not swell after hydratation as do catgut and silk: this is the reason why the conventional external Roeder knot is not suitable for such a material: once tightened, the knot can slip back. A comparative tensiometric study on various suturing materials and external slip-knots showed that for PDS the best results in terms of stress, strain, work done, energy absorption and elastic modulus were obtained with the Melzer-Buess knot (*Shimi, Lirici, Cuschieri* – personal report at the Meeting of the Royal Surgical Research Society, 1992). Such a knot cannot slip back: it is probably the only kind of slip-knot with a breaking point.

One of the major technical problems during endoscopic colorectal procedures is gas leakage after division of the bowel if no linear stapler is used for this purpose. Another technical problem is represented by the insertion of the stapler's anvil into the proximal stump when the anastomosis is not performed through a minilaparotomy. The gas proof anvil introducer has been developed in order to overcome such problems.

In this early phase of endoscopic surgery we still miss instruments specifically designed for advanced procedures. The fixation of the anvil to the stapler's spike before performing an end-to-end anastomosis is sometimes a time consuming and unsafe manoeuvre. The anvil holder allows a safe grasp while still maintaining a small degree of freedom of the anvil which makes its insertion into the shaft easier.

The management of the two stumps after division of the colon and the specimen's removal is a common concern: some surgeons perform a minilaparotomy for passing the stapler's anvil and then fixing it to the stump by an internal purse-string suture, some prefer the use of an Endo-GIA for division of the colon and closure of the stumps and subsequent anastomosis according to Knight-Griffen technique, and others prefer to make a minilaparotomy for eviscerating the colon and completing the anastomosis (8–10, 17). The cable-binding technique is a good alternative to conventional closures of the bowel stumps before performing a mechanical anastomosis. Such a technique is fast and safe and will soon be improved by providing the device with a sharp edge which cuts the exceeding tissue while tightening the cable-binder around the bowel's stump.

Because of anatomy related intraoperative complications it was necessary to change between 3 different animal models. The standardized animal trial started as soon as the required technology was available and a suitable animal model was found. The anatomical problems which occurred during the mini-pig series were due to the narrow pelvis and rectum and to problems related to the insertion of the operating rectoscope. The anatomical problems which occurred in the sheep series were related to the wide stomach which did not allow enough room for handling instruments and performing surgical manoeuvres. In both series the leak of the pneumoperitoneum caused by the division of the colon represented the major technical problem before the gas-proof "anvil introducer" was available.

The extraluminal variant of the combined laparoscopic-rectoscopic sigmoidectomy is certainly the procedure of choice in the ongoing clinical investigation: such a technique avoids any contact between the anvil and the tumour and should be performed in the case of suspected or proven malignancy. This procedure is to be preferred even in the case of stenosing diverticulitis.

A theoretical limit to the developed methodology that emerged during the research programme is the retrieval of the specimen in the case of very big neoplasms or extremely bulky bowel which cannot pass through the operating rectoscope. Further research upon retrieval systems has been planned in order to overcome such problems in the near future.

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