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Set of instruments for innovative, safe and sterile sigmoid access for natural-orifice transluminal endoscopic surgery

Ein Instrumentenset für den innovativen, sicheren und sterilen sigmoidalen Zugang für die transluminale endoskopische Chirurgie über natürliche Körperöffnungen

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Abstract

One of the current main challenges in transluminal surgery is in obtaining sterile and secure access to the peritoneal cavity. Since the transgastric approach has not fulfilled these requirements up to now, a new transcolonic surgical approach was developed to achieve these objectives and enhance the potential of transluminal surgery. A new set of instruments comprising an endoscopic trocar, a flexible obturator and a modified transanal endoscopic microsurgery device was designed to permit sterile sigmoid access for transcolonic surgery. The set of instruments has already been successfully tested in an experimental *in vivo* survival study that confirmed safety and sterility as objectives during surgical intervention. The suitability of the instruments for use in the human anatomy was confirmed by a cadaveric study.

Keywords: endoscopic instruments; transcolonic approach; transluminal surgery.

Zusammenfassung

Eine der Hauptherausforderungen in der heutigen transluminalen Chirurgie ist die Herstellung eines sterilen und sicheren Zugangs zur Bauchhöhle. Da die transgastrische Entrierung des Abdomens diese Anforderungen bis heute nicht hinreichend erfüllt hat, wird der neue Ansatz einer transkolischen Penetration eingeführt, um die definierte Zielsetzung zu erfüllen und die Potenziale der transluminalen Chirurgie zu erweitern. Ein neues Instrumentenset bestehend aus einem endoskopischen Trokar, einem flexiblen Obturator und einem modifizierten transanalen endoskopischen Mikrochirurgiegerät wurden entwickelt, um einen sterilen sigmoidalen Zugang für die transkolische Chirurgie zu ermöglichen. Das Instrumentenset konnte in einer experimentellen *In-vivo*-Studie erfolgreich getestet werden. Sicherheit und Sterilität, als wichtige Zielsetzungen, konnten während des ganzen chirurgischen Eingriffs gewährleistet werden. Die Tauglichkeit für den Einsatz in der menschlichen Anatomie wurde durch eine zusätzliche Leichenstudie bestätigt.

Schlüsselwörter: endoskopische Instrumente; transkolischer Zugang; transluminale Chirurgie.

Introduction

Transluminal endoscopic interventions via so-called natural orifices are attracting increasing interest since they allow surgical treatment without any incision in the abdominal wall and are supposed to further reduce the invasiveness of surgical operations [4, 7]. The usual access into the abdominal cavity is via the anterior gastric wall [5, 8]. For any interventional access, the following conditions have to be fulfilled:

- Obtaining access as directly as possible to the target region;
- Permitting simple straightforward introduction of instruments;
- Avoiding bacterial contamination; and
- Permitting easy and reliable closure of the entry point.

Not all of these aims could be achieved up to now. The transgastric approach is disadvantageous because of the long distance between the abdominal entry point and the natural orifice (mouth), and the longer the natural-orifice transluminal endoscopic surgery (NOTES) instrument, the more difficult it is to handle [3, 9]. Second, the entry point situated in the anterior gastric wall makes it obligatory to manipulate in a retroflexed direction for surgical interventions in the upper abdominal region.

A transcolonic or transvaginal approach would be by far more practical since the distance to the target region is much shorter and the abdominal cavity can be explored under conditions of optical correctness. Transvaginal access is an alternative approach to transcolonic, in particular transsigmoid access researched by different groups. Marescaux et al. performed the first human cho-

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lecystectomy through the vagina [6]. However, this approach is only applicable to female patients.

In contrast, the transsigmoid approach is highly unpopular among the majority of groups working on NOTES since the risk of bacterial contamination of the abdomen resulting in postoperative peritonitis is high and incisions to the colon are inclined to leak postoperatively [3].

To overcome these problems and to provide simple and practical access, we developed a set of instruments permitting a safe and sterile approach for transluminal sigmoid surgery.

Materials and methods

Technical concept

Using commercially available instruments for transanal endoscopic microsurgery (TEM), the intraabdominal part of the rectosigmoid junction can easily be reached [1, 2]. Likewise, a purse-string suture can be placed at that height of the rectum without difficulty. Using a suitable trocar that can be passed through the TEM, precise puncture of the anterior rectal wall, and thus entry into the abdomen, should also be possible. An endoscope can then be inserted into the abdominal cavity through this trocar *in situ*. After the intraabdominal procedure, the trocar is removed and the entry point is closed using the TEM device. After closure of the purse-sting suture, a linear stapler had to be applied. For this purpose, a specifically designed trocar had to be constructed. A commercial TEM device also had to be modified accordingly.

Design of a dedicated endoscopic trocar for NOTES

The length of the trocar was determined by the overall length of the TEM device and the distance between the TEM device *in situ* and the abdominal cavity. It has to have a ski-like shape owing to the curved configuration of the rectosigmoid. The inner diameter has to be wide enough to permit introduction of typically flexible endoscopes. Finally, a gas-tight valve is required to maintain the pneumoperitoneum during NOTES procedures.

The endoscopic trocar consists of three separate parts: a trocar head, a trocar tube and a mandrin (Figure 1). The trocar tube is made of a stainless steel pipe (length ~310 mm) with a diameter of 18 mm. The front end of the tube, which is inserted into the rectum, is curved. After several design prototypes, the radius of the curve was fixed to 60 mm, which allows the surgeon to set the best entry point. Using the marker engraved on the outside, the surgeon can also see where the top of the trocar is pointing and can consequently align the endoscope in the right direction. Other markers show how deep the tube is inserted. The end of the tube is connected by a bayonet coupling mechanism to the trocar head. An O-ring in between provides gas tightness. The trocar head was created using a 12-mm commercial disposable trocar. The straight tube of this trocar was removed and an adapter was fixed onto it. One side of the adapter has the counterpart of the bayonet coupling mechanism, and the other side is stuck to the trocar head. Since the outer diameter of the flexible endoscope was 13 mm, the inner diameter of the trocar head was increased to 16 mm (Figure 2). In contrast to standard laparoscopic trocars, the innovative safe and sterile sigmoid access (ISSA) mandrin is flexible. It is made of a soft plastic-tube with an outer diameter of 12 mm. The front end is made of stainless steel and has a cone of 60°. Both parts are stuck together and pinned.

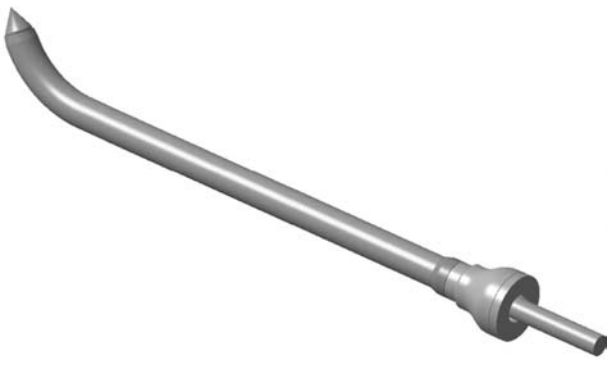

Figure 1 Schematic drawing of the endoscopic trocar with the flexible mandrin inserted.

Modification of the TEM device

The standard TEM rectoscope (Storz, Tuttlingen, Germany) has an inner diameter of 38 mm and is available with a length of 15 or 20 cm (Figure 3). The end of the rectoscope is sealed with a gas-tight cap that has four entry ports. Three ports are sealed by rubber caps so that various instruments can be inserted. The telescope is inserted through a special port. This port fixes the optical probe and seals it using a special reclosable mechanism.

This TEM device had to be modified to facilitate insertion of the ISSA trocar. In our case, two ports are used for instruments, one for the endoscopic trocar and one for the telescope. The port for the telescope is retained, with a slight change in length. The front end of the guiding tube is shortened to a length of 93 mm so that the endoscopic trocar with a ski-like shape can be inserted (Figure 4). Both instrument ports are repositioned. The inner diameter of the ports is reduced to 6 mm to permit augmentation of the trocar port. The endoscopic trocar is 18 mm in diameter; therefore, the trocar port was set to 19 mm and placed centrally. When the trocar port is not in use, it can provide access for other laparoscopic instruments, such as a stapler, retrieval bag, etc. The oblique tip of the original TEM device was turned by 180° to improve the exposition of the anterior wall of the rectum.

Results

Surgical procedure and application of the instruments

The surgical procedure for ISSA intervention consists of four consecutive steps.

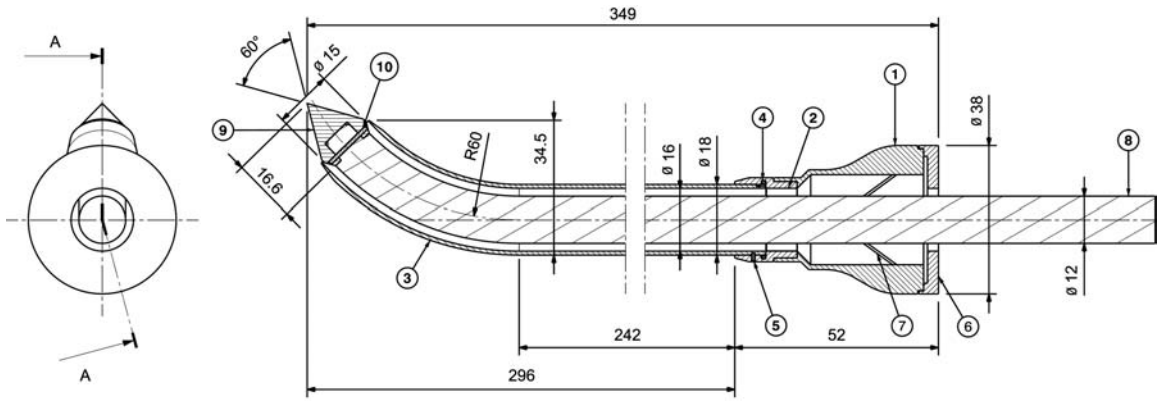

Figure 2 Cross-section of the ISSA trocar with inserted mandrin.
(1) Trocar head, (2) tube adapter, (3) trocar tube, (4) O-ring seal, (5) bayonet mechanism, (6) front cap, (7) trocar valve, (8) flexible mandrin, (9) conic front end, and (10) mandrin pin. Cross-section A–A: measure 1:1.

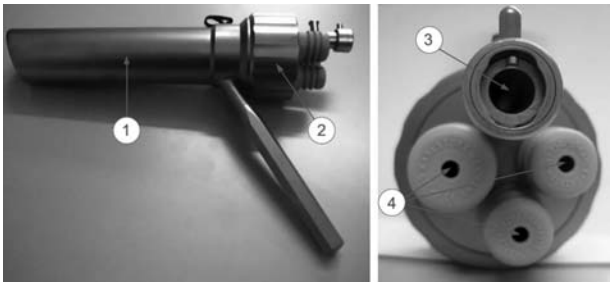

Figure 3 Standard transanal endoscopic microsurgery (TEM) device (Storz).
(1) Rectoscope with oblique tip, (2) TEM cap, (3) optical port, and (4) instrument ports.

Step 1 Taurolidin solution, a decontaminating fluid widely used in general surgery to prevent and treat peritonitis, is instilled via a Veress needle into the abdominal cavity.

Step 2 The rectosigmoid is entered using the adapted TEM device as described above. The ventral aspect of the rectosigmoid junction is identified and marked through the trocar port by short diathermic application. A rigid ultrasound probe is then inserted through the trocar port to assess the third dimension of the intended entry point. As soon as the surgeon confirms that the entry point is covered by ascites and that the small bowel loops are at a safe distance, a purse-string suture is applied using TEM instruments.

Step 3 The sterile trocar tube with the flexible mandrin is introduced through the trocar port of the TEM device (Figure 5). With its sharp tip, the entry point is perforated to provide entry into the abdominal cavity. As soon as the peritoneal cavity is penetrated, the mandrin is removed and then the trocar head is connected to the outer end of the endoscopic trocar. Then the sterilized flexible endoscope can be inserted into the abdomen to perform the surgical procedure (Figure 6).

Step 4 The flexible endoscope is withdrawn once the surgical procedure is complete. The endoscopic trocar is subsequently removed as well. Finally the purse-string suture is closed and the small nipple resulting from the purse-string is secured using a linear stapler. After inserting the linear stapler through the trocar port of the adapted TEM cap, the slight elevation of the rectal wall resulting from the purse-string suture is excised by one or two applications of the stapling device. Thus, tight and reliable closure of the entry site is achieved.

Cadaveric study

To confirm the clinical applicability, transsigmoid entrance into the peritoneal cavity was attempted in five

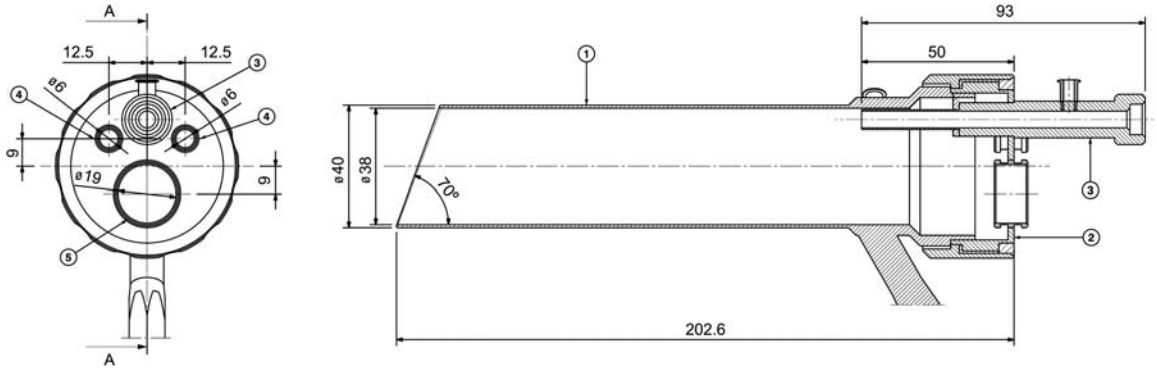

Figure 4 Cross-section of the new transanal endoscopic microsurgery (TEM) device.
(1) Rectoscope, (2) TEM cap, (3) shortened optic port, (4) instrument ports, and (5) trocar port. Cross-section A–A: measure 1:1.

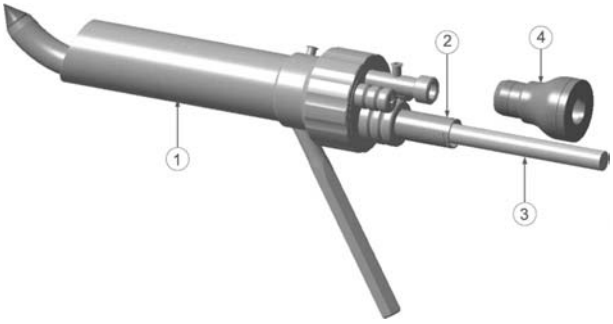

Figure 5 Schematic drawing of the new transanal endoscopic microsurgery (TEM) device with inserted endoscopic trocar. (1) TEM trocar, (2) trocar tube, (3) flexible mandrin, and (4) trocar head with the adapter.

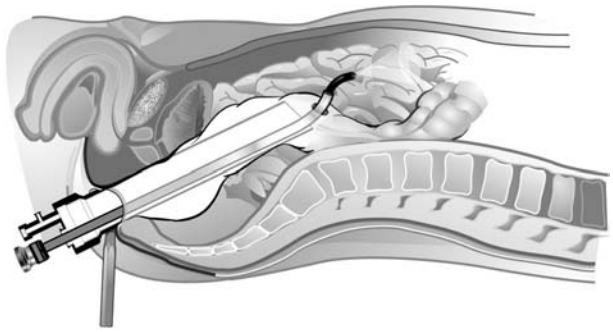

Figure 6 Surgical procedure involving innovative, safe and sterile sigmoid access.

Figure 7 Application of innovative, safe and sterile sigmoid access in a cadaveric study.

human cadavers (body mass index 18–33 kg/m^2). As soon as the abdomen had been opened during necroscopy, the device was introduced into the rectosigmoid as described above. In all five instances, the tip of the trocar entered the space of Douglas without any laceration of adjacent structures (Figure 7).

According to the Ethics Committee of Klinikum rechts der Isar, the cadaveric study did not require authorization.

Discussion

The newly designed set of instruments is based on an existing TEM device. The use of TEM has greatly increased in the last decade [1, 2] for surgical techniques that involve dissection and suturing within the rectal lumen. TEM does have some limitations, such as limited degrees of freedom and a working distance of only up to 15 cm from the anal verge, but these are irrelevant within the scope of the present study.

The aim of this research was to develop a new technology to allow insertion of a flexible endoscope through the sigmoid into the abdominal cavity. An interdisciplinary working team of clinicians and engineers first suggested ideas for the instruments, which then had to be improved to an applicable prototype. This prototype consists of a modified TEM trocar and an additional endoscopic trocar that serves as an overtube.

The set of instruments was successfully applied in an experimental study [9] that confirmed their simple handling. The goals of a functional mechanism with simple assembly and low-cost parts were successfully achieved.

NOTES interventions require gas-tightness. This requirement was realized with an adaptation of a commercially available laparoscopic trocar and simple sealing. An experimental study proved that the designed endoscopic trocar is gas-tight.

Sterility is a major precondition for surgical intervention and is an important consideration in the design of medical instruments. Our experimental set of instruments can be easily and reliably gas-sterilized [9].

Although some features of the design still have to be improved, the ISSA devices allow sterile and standardized entrance into the peritoneal cavity. A wide spectrum of NOTES procedures, in particular in the upper and middle abdomen, should be easily feasible.

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