



Application of a custom-made single-incision sealing device in laparoscopic surgery for totally extraperitoneal herniorrhaphy: initial experience

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Background: In this research, the safety and feasibility of single-incision laparoscopic surgery for total intraperitoneal herniorrhaphy (SILS-TEP) was clarified through a customized single-port device.

Methods: A 2.5 cm curved incision was made along the lower umbilical margin. The subcutaneous fatty tissue was removed by electrotomy or blunt dissection to form a 5.0 cm preperitoneal space under the posterior sheath. The Iconport single-hole device silicone sealing sleeve was wedged under the posterior rectus sheath and inflated with CO₂ to dilate the anterior peritoneal space toward the lower abdomen. According to the standard method of laparoscopic total peritoneal hernia repair, conventional laparoscopic instruments were used to complete the operation.

Results: Successful SILS-TEP hernia repair was performed in 63 patients. The mean operative times for unilateral indirect hernia were 65.5 [40–110] minutes. The mean operative times for unilateral direct hernia, and femoral were 51.3 [36–83] minutes, respectively. Six seroma cases were seen during the 1- to 32-month follow-up periods, and all patients recovered after conservative treatment. No other major complications were observed. The mean postoperative hospital stay was 3.3 days.

Conclusions: With the assistance of a suitable single-port laparoscopic device, SILS-TEP umbilical incision under the posterior rectus sheath is a safe and feasible method.

Keywords: Custom-made single-port device; Iconport; single-incision laparoscopic surgery (SILS); total extraperitoneal herniorrhaphy (TEP)

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Introduction

Laparoscopic total extraperitoneal herniorrhaphy (TEP) is an effective surgical method for repairing an inguinal hernia. TEP is complicated because it is necessary to establish the preperitoneal space first and then introduce the camera and surgical instruments. During the establishment

of the preperitoneal space, physicians with insufficient surgical experience may cause peritoneal rupture because they cannot distinguish the tissue layers clearly. While single-incision laparoscopic surgery for TEP (SILS-TEP) can effectively complete surgery, it can reduce the number of abdominal puncture holes, and reduce the trauma, pain

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Figure 1 Iconport single-incision sealing device (the obverse side).



Figure 2 Iconport single-incision sealing device (underside).

and related complications of surgery (1). The first SILS-TEP was performed in 2008 (2); thus, SILS-TEP has been in development for 13 years. Because of the difficulty of the operation, it has been slow to develop and spread over the past decade (3-15).

In 2013, our team developed an Iconport laparoscopic single-incision sealing instrument (United States Patent No. US9,393,003B2). This instrument could be applied to many operations, such as transabdominal preperitoneal (TAPP) laparoscopic herniorrhaphy, laparoscopic cholecystectomy, gastroduodenal ulcer perforation, and transumbilical single-port laparoscopic appendectomy.

Over 200 operations have been performed so far (16,17). During these operations, the abdominal wall tissue adjacent to the umbilicus is cut open such that the tissue under the linea alba, which is composed of the peritoneum, preperitoneal fat and preperitoneal fascia, can be seen; it seems that these tissues are thick in 70–80% of patients but thin and prone to damage in 20–30% of patients. After fully understanding the anatomy of the umbilical abdominal wall and the preperitoneal space, the authors improve the instrument of SILS-TEP to reduce the complications. In 2017, the authors attempted to conduct TEP surgery to treat TEP by cutting the umbilical abdominal wall via the posterior rectus abdominis sheath. A total of 63 cases of SILS-TEP underwent surgery from February 2019 to October 2021. We present the following article in accordance with the STROBE reporting checklist (available at <https://atm.amegroups.com/article/view/10.21037/atm-21-6809/rc>).

Methods

Materials

The principal author used a single-hole device named Iconport (*Figures 1,2*) to close the incisions and complete SILS-TEP through umbilical incision via the posterior rectus abdominis sheath. The Iconport single-hole device is comprised of an operating panel made of medical polypropylene plastic and an incision protective sleeve made of medical silica gel. The two parts were installed through a clamping ring, which can be disassembled and reassembled during surgery to facilitate specimen collection. The incision sealing sleeve, made of medical silica gel, can have a diameter of 1.0, 2.0, 3.0 or 4.0 cm. In general, a diameter of 2.0 cm is selected for SILS-TEP in adults. There are 4 port accesses in the panel for the laparoscopic instruments and the camera. The camera enters through the middle access port. Laparoscopic surgical instruments with diameters of 5 or 10 mm can be interchangeably used with the other port accesses. The study was registered on the Chinese clinical trial registry (Identifier: ChiCTR1900023056).

Patients

A total of 63 patients who underwent SILS-TEP at the Affiliated Hospital of the Medical School of Ningbo University were enrolled from February 16, 2019 to

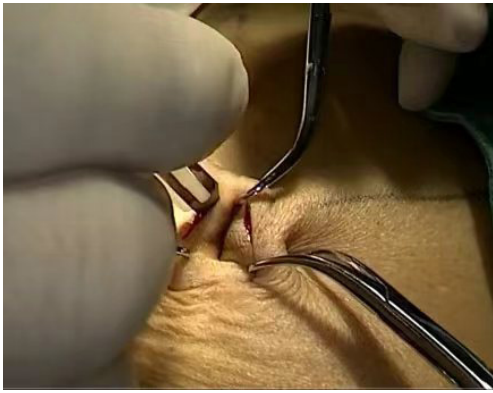


Figure 3 Navel incision.



Figure 4 Insertion of the silica gel seal sleeve inside the incision.



Figure 5 Peritoneal space under the posterior rectus abdominis sheath in an umbilical incision. This image is published with the participant's consent.

October 4, 2021. Inclusion criteria: patients diagnosed with inguinal hernia. The exclusion criteria were as follows: (I) age <20 years; (II) acute bowel-incarcerated hernia; (III) retroperitoneal surgery history; and (IV) cardiopulmonary dysfunction. In the control patients, open hernia repair was performed. In this research, short-term outcomes were collected and analyzed. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This study was approved by the research ethics

committee of the Affiliated Hospital of the Medical School of Ningbo University (No. 2019KY0402) and informed consent was obtained from all participants in this study. All information in this study was approved for publication by all participants.

Surgical technique

After general anesthesia, a supine position is taken. In step 1, a skin incision is made. A single 2.5-cm-long curved incision is made along the lower umbilical border (*Figure 3*). The subcutaneous tissue is incised to reveal the aponeurotic layer.

In step 2, the operating space is created in the preperitoneal space behind the linea alba under direct vision. A small incision of 0.5 cm is transversely cut along the surface of the linea alba. Vascular forceps are inserted facing the pubic symphysis and used to gently open the preperitoneal space. Furthermore, with the assistance of an electrocutter, the adhesion between the deep surface of the aponeurosis and the preperitoneal tissue is gradually cut. The posterior sheath and linea are separated by electrocution or blunt dissection to create a 5.0 cm preperitoneal space.

In step 3, the silica gel incision seal sleeve of the single-hole device is installed below the aponeurotic layer of the incision (*Figure 4*). The silica gel sealing sleeve of the Iconport single-port device is inserted under the posterior rectus abdominis sheath. As long as the silica gel sheath is installed below the aponeurotic layer of the incision, the operation could commence smoothly, even if there is not enough space for the silica gel sheath to open naturally. As the camera is inserted into the incision, the silica gel seal is held open, and the layers of tissue are identified in the field of view (*Figure 5*). The superficial tissue of the preperitoneal fascia is cut transversely along the deep surface of the aponeurosis using an electrocoagulation device, and the space within the preperitoneal space is gradually increased (*Figure 6*).

In step 4, the anterior peritoneal space adjacent to the umbilicus is enlarged. The preperitoneal space is dissected progressively with conventional straight and rigid laparoscopic instruments with CO₂ gas expansion. It is difficult to separate the fused tissue between the preperitoneal tissue and the deep surface of the aponeurosis at the outer margin of the rectus abdominis, but the area near the outer margin of the rectus abdominis is easier to separate to access the preperitoneal space.

In step 5, the preperitoneal space is expanded to expose



Figure 6 Intraoperative laparoscopic view of the preperitoneal space.

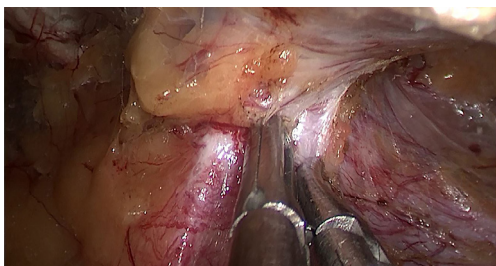


Figure 7 Initial view of the Retzius space.

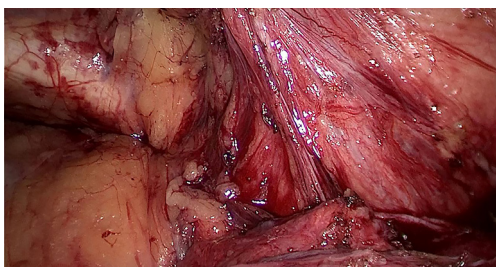


Figure 8 Intraoperative laparoscopic view of the preperitoneal space.

the Retzius space. Generally, the Retzius space can be exposed easily (*Figure 7*).

In step 6, the Bogros space is broadened. The outside of the internal inguinal ring is first separated, and then the laparoscopic operating instrument could be inserted into the Bogros space. When separating the right Bogros space, the surgeon uses the electrocoagulation hook in the left hand to operate more smoothly.

In step 7, the hernia sac is stripped. In the case of an indirect hernia in men, the hernia sac is carefully separated from the spermatic cord and reduced from the inner ring by gentle traction and dissection. When the hernia sac has been separated and detached from the spermatic cord,



Figure 9 Mesh deployed to cover the whole myopectineal orifice.

we select two adjacent channels on the panel and retain the optical fiber of the camera between the handles of the two laparoscopic instruments for flexible processing. In female patients, the peritoneum is dissected from both sides of the uterine round ligament to separate the hernia sac completely and to keep the hernia sac intact. When peritoneum or hernia sac tears occur, if the peritoneum tears are large, we suture the peritoneum; if the tear is small, we use an endo-clip.

In step 8, the mesh is placed. When we create the preperitoneal space (*Figure 8*), we can see the entire myopectineal orifice, and we can see the hernia sac and separate it from the spermatic cord. A 12×14 cm polypropylene mesh (EthicoH ULTRAPRO, Johnson, Norderstedt, Germany) is inserted and extended to cover the entire myopectineal orifice (*Figure 9*). Other meshes with the same function can also be used. No fixation is required for a flat mesh.

In step 9, the incision is sutured and covered. The linea alba is sutured intermittently with a 2-0 absorbable suture, and the skin is sutured consecutively with 4-0 absorbable sutures (*Figure 10*). The strips are inserted into the umbilical hole to assist in applying pressure on the incision, and a covering is applied to the incision.

Data collection

The following data were recorded: age, sex, body mass index (BMI), American Society of Anesthesiologists (ASA) score, the position of the hernia, surgery time, blood loss, conversion, postoperative hospital stay, follow-up time, complications, and hernia recurrence. The pain scores were checked 1 day after the surgery by a member of the team using a visual analog scale (VAS) (18,19). Some patients were followed up with outpatient visits, while



Figure 10 Photograph of the postoperative incision.

others were followed up by telephone. The last time of follow-up data were used among patients who could not be contacted.

Statistical analysis

The data were recorded in Excel. The mean value was calculated with GraphPad Prism 6.0. The data are presented as the means \pm SDs or as numbers (percentages).

Results

Sixty-three patients successfully underwent SILS-TEP hernia surgery. The general information of the patients is presented in *Table 1*. The mean age was 56.4 [27–81] years, and their mean BMI was 23.5 [18.6–35.6] kg/m². The operation and post-operation data are shown in *Table 2*. The mean operation time was 65.5 [40–110] and 51.3 [36–83] minutes for unilateral indirect hernia and for unilateral direct or femoral hernia, respectively. The mean operation time was 83.7 [60–150] minutes for bilateral hernias. The mean operation pain VAS score on postoperative day 1 was 1.8 \pm 0.9. One patient experienced internal spermatic vessel injury, but there were no related complications in the following 15 months. Peritoneal rupture occurred in 11 cases, and the distal indirect hernia sac was amputated in 3 cases. No other intraoperative complications existed. Three seromas were observed during the 1- to 32-month follow-up duration, and all recovered after conservative treatment. No other major complications were found in the follow-up months. No death

Table 1 Patient demographics and hernia characteristics

Variables	Value
Number of patients	63
Male	56
Female	7
Mean age (years), mean [range]	56.4 [27–81]
Mean BMI (kg/m ²), mean [range]	23.5 [18.6–35.6]
Median ASA, mean [range]	1.1 [1–2]
Site of hernia	63
Right	29
Left	26
Both	8
Type of hernia	71
Indirect hernia (Gilbert type)	60 (Gilbert I, 19; Gilbert II, 26; Gilbert III, 15)
Direct hernia (Gilbert type)	7 (Gilbert IV, 3; Gilbert V, 4)
Femoral hernia (Gilbert type)	4 (Gilbert VII, 4)
Scrotal hernia	4
Recurrent hernia	0
Incarcerated hernia	0

BMI, body mass index; ASA, American Society of Anesthesiologists.

or recurrence occurred. The mean postoperative hospital stay was 3.3 days.

Discussion

TEP surgery is typically performed through the anterior space of the rectus abdominis posterior sheath on the hernia side to create the initial preperitoneal space followed by pneumoperitoneum and further laparoscopic herniorrhaphy. It is difficult to conduct laparoscopic surgery via an umbilical incision under the posterior rectus abdominis sheath because of the possibility of causing peritoneal damage when the preperitoneal space is created under the sheath. The principal author used a single-port device named Iconport to seal the incision and complete SILS-TEP. A small preperitoneal space is sufficient for the silica gel seal sleeve of the Iconport to create the pneumoperitoneum for laparoscopic surgery. The pneumoperitoneum requires less space in the initial preperitoneal space. As a result, the incidence of

Table 2 Summary of the operative and postoperative data

Variables	Value
Operative time (minutes), mean [range]	
Indirect	65.5 [40–110]
Direct or femoral	51.3 [36–83]
Both	83.7 [60–150]
VAS score (postoperative day 1), mean \pm SD	1.8 \pm 0.9
Accidental peritoneal rupture	11
Keep the uterine round ligament intact	8
Hernial sac amputation	4
Ductus deferens injury	0
Internal spermatic vessel injury	1
Inferior epigastric vessel injury	0
Corona mortis bleeding	0
Seroma	3
Hematoma	0
Delirium	0
Chronic pain	0
Testicular atrophy	0
Urinary retention	0
Umbilical hernia	0
Recurrence	0
Mean postoperative hospital stay duration (days)	3.3

VAS, visual analog scale.

subincision peritoneal rupture or intraperitoneal bleeding is significantly reduced compared with other techniques. After the pneumoperitoneum is completed, it is relatively easy to enlarge the preperitoneal space with the assistance of a microscope and the cooperation of two laparoscopic surgical instruments under good tension.

Most surgeons believe that single-incision laparoscopic operations are difficult. In fact, SILS-TEP has both advantages and disadvantages. During SILS-TEP, the laparoscopic surgical instruments and camera enter the surgical area via the same incision, and an instrument must be pressed against the peritoneum at all times to maintain visibility in front of the lens, even if the peritoneum is ruptured at the start of the surgery. Peritoneal rupture could prolong the operation time of SILS-TEP, but there

is no need to switch to TAPP surgery. In SILS-TEP, one instrument is used to pull or press on the peritoneum to assist in exposing the surgical field, and another instrument performs the tissue separation, thereby widening the preperitoneal space. Mobility is guaranteed in this surgical procedure because only one instrument moves frequently.

When an indirect hernia sac is dissected, there is some mutual interference during the operation of the two laparoscopic instruments. In practice, the author found that the Iconport single-hole device can effectively solve the problem of mutual interference between two laparoscopic instruments during SILS-TEP. When the operator selects two adjacent holes in the operating panel, alternations between two laparoscopic instruments can be achieved. Thus, the two laparoscopic instruments can be accessed at nearly parallel angles to the preperitoneal space. The front end of the two devices can be used flexibly.

Rigid materials were used to create the Iconport panels. The diameter of the operation hole is 15 mm, and the diameter of the laparoscopic instrument is 5 mm, so the laparoscopic instrument has enough inclination angle to perform the operation. Due to the effective support of the sidewall of the panel operating hole, the surgeon can complete the basic operation stably and effectively, even if the main operation is performed with an instrument used by the left hand. As previously reported, the majority of SILS-TEP surgeries are performed in the anterior space of the posterior rectus sheath on the hernia side (2,4–15), which has the advantage that the peritoneum near the incision is not easily injured. The authors found that the preperitoneal space formed by an umbilical incision under the posterior sheath of the rectus abdominis is a more advantageous method, especially in bilateral hernia surgery, because there is no need to cut the posterior sheath of the rectus abdominis at the semilunar line. When a laparoscopic operation is performed in the posterior space of the rectus abdominis posterior sheath, the instrument is less affected by the rectus abdominis sheath; in contrast, when the same operation is performed in the anterior space of the rectus abdominis posterior sheath, it is inevitable that the linea alba will have a negative effect on the movement of the laparoscopic instrument.

Previous studies have shown that there is a certain probability of umbilical incisional hernia after SILS-TEP surgery (9–11). The authors believe that the method of incising the linea alba at a certain distance below the umbilicus used in this study is quite different from the method of incising the deep surface of the umbilicus in

previous studies (9-11). No umbilical hernia complications were observed in the present study. The author observed that during SILS-TEP, the peritoneum and the posterior sheath were compactly fused at the lateral margin of the rectus abdominis on both sides, which means that the peritoneum and the posterior sheath are compactly fused at the semilunar line. The area between the lateral margin of the rectus abdominis on both sides is the open space under the posterior sheath. There is adipose tissue down the midline. The process of dissecting the preperitoneal space from the umbilical incision to reveal the Retzius space is easily accomplished. As the peritoneum is dissected from the posterior sheath of the rectus abdominis along the lateral margin of the rectus abdominis, the lateral Bogros space is gradually revealed.

Hence, the author believes that the correct anatomical level to be followed during SILS-TEP is easier to identify via the rectus abdominis posterior sheath approach than by other approaches. If the anatomical characteristics of the anterior peritoneal space under the posterior sheath have been controlled and there is a way to create the anterior peritoneal space behind the posterior sheath without damaging the peritoneum, it is not necessary to perform SILS-TEP surgery from the anterior posterior sheath because the surgeon is no longer concerned about the peritoneal damage near the incision and knows how to avoid it.

Thus, there were some suggestions of Iconport SILS-TEP: (I) this technology could be applied in various abdominal wall hernias; (II) a small preperitoneal space is sufficient for the silica gel seal sleeve of the Iconport to create the pneumoperitoneum; (III) preperitoneal space formed by an umbilical incision under the posterior sheath of the rectus abdominis is a more advantageous method; (IV) Iconport is an effective device to treat abdominal wall hernias.

In this study, the mean operation time for unilateral indirect hernia was 65.5 minutes, the mean operation time for unilateral direct hernia or femoral hernia was 51.3 minutes, and the mean operation time for bilateral hernia was 83.7 minutes. The average operation time was directly related to the surgical experience of the surgeon. There was no need to increase the size of the auxiliary operation hole or to change to a TAPP operation for other reasons. One patient experienced internal spermatic vessel injury, but no other intraoperative complications occurred. Three seroma cases were observed during the 1- to 32-month follow-up period, with no other major postoperative complications.

There are obvious advantages and shortcomings of

SILS-TEP. SILS has been applied in many surgeries, like appendectomy, cholecystectomy, rectal surgery and gynecological surgery due to low surgical trauma, post-operation pain and related complications. As for limitations, transumbilical single-hole laparoscopic surgery is a difficult operation for most surgeons and it requires a steep learning curve. Since the author is the developer of this Iconport single-hole device and has more than 200 cases of experience in transumbilical single-hole laparoscopic surgery, the author can complete SILS-TEP relatively smoothly, but this may not be generalizable to other surgeons. The sample size of this study was small, and the follow-up time was short, so there are some limitations regarding the observations of intraoperative and postoperative complications.

Conclusions

The authors believe that it is safe and feasible to perform SILS-TEP via an umbilical incision under the posterior rectus abdominis sheath with the assistance of a suitable single-hole laparoscopic device. If we can create a preperitoneal space through an umbilical incision under the posterior rectus sheath to perform inguinal hernia repair and the incision is hidden, then we have the opportunity to use the same method to correct other types of abdominal wall hernias and achieve good results. Therefore, the method of creating the preperitoneal space through an umbilical incision into the back of the rectus abdominis has broad application value.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at <https://atm.amegroups.com/article/view/10.21037/atm-21-6809/rc>

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Conflicts of Interest: All authors have completed the

ICMJE uniform disclosure form (available at <https://atm.amegroups.com/article/view/10.21037/atm-21-6809/coif>). XW reports the patent of No. US 9,393,003,B2. XW is the inventor of the Iconport single-hole device. He oversaw the completion of the main content of the study. The other authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This study was approved by the research ethics committee of the Affiliated Hospital of the Medical School of Ningbo University (No. 2019KY0402) and informed consent was obtained from all participants in this study. All information in this study was approved for publication by all participants.

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