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Experimental use of a novel single-port gasless laparoendoscopic operative field formation device

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HIGHLIGHTS

- Traditional carbon dioxide laparaendoscopy is a high risk surgery.
- The existing gasless laparaendoscopies have attendant poor visibility of the abdominal cavity.
- We developed an inflatable device for gasless laparoscopic operation field formation (LOFF).

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ABSTRACT

Introduction: Traditional laparaendoscopic surgery using CO2 pneumoperitoneum is associated with complications and the existing gasless laparaendoscopic surgery has shortcomings such as poor visibility in the operation field. To overcome the disadvantages of the current lifting gasless laparaendoscopic operation platforms, we developed an inflatable device for gasless laparoscopic operation field formation (LOFF) that can be internally installed and applied in practice.

Methods: We initially designed operation platforms for gasless laparaendoscopic single-port (GLESP) surgery. Subsequently, a triangular prismatic LOFF device was selected and applied successfully to GLESP cholecystectomy of five pigs. Ultimately, using pigs as a model, three surgical approaches (LOFF-assisted laparaendoscopic single-site (LOFF-LESS), LESS surgery, and traditional lifting (GLESP) were compared, and the advantages and drawbacks of inflatable devices for gasless laparoscopic operation field assessed.

Results: The use of the LOFF device in GLESP cholecystectomy was first evaluated. The time for surgical space formation (4.4 ± 1.2 and 4.8 ± 1.0), the operating time for gallbladder removal (25.2 ± 4.8 and 25.4 ± 2.7), and the loss of blood (9.4 ± 3.1and 9.2 ± 2.4) was similar between LESS and LOFF, respectively (Table 2). In contrast these parameters were higher in GLESP (6.6 ± 1.0, 30.3 ± 4.4 and 10.1 ± 2.0, respectively. The LOFF-LESS surgery exhibited a clearer exposure of the surgical field and shorter operating time than the GLESP surgery. LESS technology showed less postoperation pain, fast recovery, and extremely high cosmetic satisfaction.

Conclusion: The LOFF device provides a safe, effective, and feasible operation platform that can be internally installed and inflated for GLESP surgery during cholescytectomy in animal models.

1. Introduction

Since the establishment of laparaendoscopic technology, a series of laparaendoscopic techniques have been developed, including the traditional laparaendoscopic technique, the laparaendoscopic single-site (LESS) technique, the gasless laparaendoscopic technique, and the gasless laparaendoscopic single-site (GLESP) technique, as well as other newly emerging laparaendoscopic techniques. In traditional laparaendoscopic surgery, the surgical space is formed using carbon dioxide (CO_2) pressure to push aside the surrounding tissue in the body cavity, allowing satisfactory exposure of the operation field. Indeed, CO_2 is the most frequently gas for insufflation into the abdomen during

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laparoscopic abdominal surgery. However, it is associated with complications. However, accumulating clinical data reveal the danger of pneumoperitoneum and the high risks of its associated complications such as adverse effects on the circulatory system [1], the respiratory system [2], blood coagulation – especially venous thrombosis - [10], and the nervous system [11] as well as increasing the risk of maternal-foetal hypoxia [3], and the risk of seeding of free tumour cells in the abdominal cavity [4]. However, the complication rate of pneumoperitoneum has not been prospectively studied in small animals. Therefore, although traditional surgical approaches continue to be applied and promoted in clinical practice researchers have begun to explore devices for gasless operation. To date, the gasless technique has been used in various surgeries [5–8], including laparaendoscopic radical resection for colorectal cancer, gastrectomy, hepatectomy, and other surgical procedures. Despite the fact that the laparaendoscopic gasless technique offers a number of advantages, it has not been widely used in clinical practice. A major reason for this is that lifting the anterior abdominal wall by mechanical force can cause the lateral walls to move towards the middle and push the gut towards the operation field, thus reducing the surgical space and resulting in poor exposure of the operation field [8]. To overcome this disadvantage, our research group developed a device for gasless laparoscopic operation field formation (LOFF) and tested its use in LOFF-aided LESS operations (LOFF-LESS surgeries) in animal experiments.

2. Methods

2.1. Research and development of the LOFF operation platform

The main components of the proposed device include an inflating hose, a guiding rod, an extension frame, a top platform, and a supporting body (Fig. 1).

2.1.1. The inflating hose and guiding rod

The inflating hose is a tubular hose, 0.3 cm in diameter, made of medical-grade plastic; it is used for the inflation and deflation of the supporting body. The guiding rod is primarily composed of rigid material and is used to place the supporting body in the surgical area.

2.1.2. The platform and the extension frame

The platform is a plastic component with a round surface 2 cm in diameter. Five round holes are placed at intervals on the platform to permit access of surgical tools, the endoscope, and the inflating hose during the operation. The extension frame, which is made of medical thermoplastic polyurethane (TPU) materials, not only connects the platform and the supporting body but also enables depth adjustment of the supporting body within the abdominal cavity to accommodate animals of different body sizes.

2.1.3. The supporting portion

This part is made of medical TPU material and has a hollow triangular prismatic shape (height, 10 cm; two ends, equilateral triangular shape with 11-cm-long sides). This part not only allows the formation of the operation field and space but also prevents entry of the surrounding organs into the operation field.

2.1.4. Application instructions

First, with assistance from the guiding rod, the LOFF device is inserted into the abdominal cavity through a 2.5-cm-long arch-shaped incision in the umbilical region. The device is moved along the anterior abdominal wall until it reaches the surface of the liver, at which point the liver is pulled back until the gallbladder is exposed. Next, the supporting body of the device is inflated through the inflating hose to form a hollow triangular prismatic surgical space at the right visceral surface of the liver. Subsequently, LOFF-LESS surgery is performed under laparaendoscopic monitoring. After the surgery is completed, the supporting body is deflated by allowing the gas to flow out through the inflating hose; the entire LOFF device is then removed through the incision in the umbilical region.

2.2. Animal experiments

Small domestic pigs (body weight 32–35 kg) were provided by the Laboratory Animals Center of Tong-ji University. The animals were housed in an environment with a 12-h light/dark cycle at a controlled temperature and humidity and were given free access to standard feed and clean water. All experiments were carried out under the Approval of the Ethical Research Committee at Tong-ji University and Shanghai province.

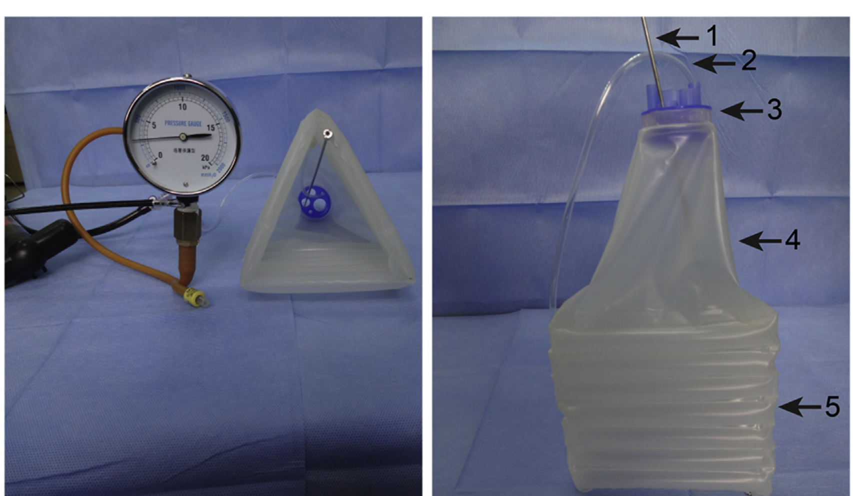

Fig. 1. Structure of the LOFF device. 1. Guiding rod; 2. Inflating hose; 3. Platform; 4. Extension frame; 5. Supporting body.

2.3. Evaluation of compression-induced damage to surrounding internal organs caused by the LOFF device

Two Landrace pigs (one female and one male), with an average age of 5.05 ± 1.36 months and an average body weight of 34.57 ± 2.43 kg, were selected. The pigs were fasted for 12 h and were not allowed to drink water the morning before surgery. The pigs received intramuscular injections of atropine (0.02 mg/kg) and ketamine (10 mg/kg). In addition, pentobarbital (20 mg/kg) was intravenously injected to induce anaesthesia. After tracheal intubation, 1.5% isoflurane was administered to maintain anaesthesia. After general anaesthesization the pigs were fixed in a supine position and were subjected to conventional disinfection and sterile draping. A 20- to 25-mm-long arch-shaped incision was made along the right side of the umbilicus, and the abdominal wall was opened layer by layer in a direct view. Subsequently, two LOFF devices were inserted through the incision and placed at the upper right and the lower left of the abdominal cavity. The devices were inflated through the inflating hose using an air pump, and inflation was maintained for 2 h after successful operation field formation. Meanwhile, the endoscope was inserted to observe ① whether the LOFF device could successfully form an operation field and ② whether the field changed 2 h after its initial formation. Two hours later, tissues from the surrounding organs contacting the LOFF device were partially removed for pathological examination to examine the damage. The same surgeon (Dr. Hai Hu) performed surgeries on both the control and the experimental ('test') groups. Control and test tissues were used and assessed by two pathologist for double blind histo-pathological evaluation. 'Control' denotes tissues harvested from the intestine, stomach, and omenta after pneumoperitoneum-aided LESS surgery; 'Test' denotes tissues harvested from the intestine, stomach, and omenta after LOFF-LESS surgery.

2.4. Development of the LOFF device

To develop an ideal LOFF device, we tested six prototypes with different shapes: a rigid wide sheet, a wire-like shape with a flexible base, a flexible wire-like shape, a hollow conical shape, a hollow cylindrical shape, and a hollow triangular prismatic shape (Fig. 4). After a test using animals, we found that the first four types either could not form a surgical space or could only form a surgical space that offered extremely poor visibility in the abdominal cavity. The hollow cylindrical and hollow triangular prismatic devices successfully formed a surgical space after inflation. Compared with the hollow cylindrical device, the hollow triangular prismatic device resulted in superior exposure of Calot's triangle in the upper abdominal cavity. In particular, if the muscle tonus in the abdominal muscles was high, the inflated hollow cylindrical device became oval and led to a poor exposure of Calot's triangle. However, the hollow cylindrical device was greatly advantageous in exposing pelvic organs because the adequate space in the lower abdominal cavity allowed the device to retain its normal round shape after inflation, in particular after the use of muscle relaxants.

2.5. Construction of the LOFF device

To identify materials suitable for the construction of the LOFF device, we tested four different materials. The first material tested wasan0.18-mm-thick TPU material produced by DingZing Chemical Industrial Co. Ltd (FT-1029C, Taiwan). However, half of the devices made of this material ruptured when they were inflated to a pressure of 80 kPa. Therefore, a polyvinyl chloride (PVC) material with higher strength was tested. The PVC-made device was later abandoned because it broke easily when it contacted the heated electrocautery hook during operation. The third material tested was polyester fabric with a thickness of 0.28 mm. Using this material, the inflated supporting balloon remained intact after contact with the electrocautery hooks and surgical suturing needles, thus significantly improving the device's stability. However, it was difficult to move the polyester fabric device to adjust its position in the abdominal cavity because of the relatively high frictional force exerted by the material. The fourth tested material was "nylon 70D double-sided TPU"; the interior of this material was made of nylon fabric, and the exterior was made of TPU. This is currently the most suitable material available for LOFF devices. Our next step was to add a hydrophilic coating on the surface of the exterior TPU material to increase the smoothness of the device [16,17]. The new design is currently being tested in animals to investigate the possible effects of coating falloff in the body.

2.6. Use of the LOFF device in GLESP cholecystectomy

Five healthy Landrace pigs (three females and two males), with an average age of 5.05 ± 1.36 months and an average body weight of 34.57 ± 2.43 kg, were used. The procedures used in pre-operation preparation and anaesthesia were the same as described above. A conventional laparaendoscopic instrument, i.e., a high-definition endoscope with an adjustable probe head (EndoEYE™LTF-VP, Olympus), was used for the surgery. By inflating the supporting body of the device through the inflating hose using the air pump, an operation field for laparaendoscopic cholecystectomy was formed. While the pig was kept in the same supine position, the surgical tools were inserted into the surgical space, and the gallbladder/ampulla were held with a grasper and lifted upwards to the right to expose Calot's triangle. Subsequently, after careful observation of the anatomic relationships among the gallbladder/ampulla, cystic duct, common bile duct, and hepatic common duct, the gallbladder artery in Calot's triangle was separated and severed at a site close to the gallbladder using an ultrasonic scalpel. Subsequently, the gallbladder duct was clamped with a 0.5-cm plastic clamp, followed by separation of the gallbladder bed and removal of the gallbladder using an electrocautery hook. The blood and smoke in the operation field were immediately removed by rinsing and aspiration, respectively, and the device removed. After an exploration to ensure that no abnormalities were present in the gallbladder bed or in Calot's triangle, the entire gallbladder was placed in a specimen bag and removed through the incision in the umbilical region. After examination to ensure that there was no bleeding at the puncture site, the skin incision was sutured.

2.7. Measurements for the comparison of LESS, GLESP and LOFF-LESS surgeries in animals

Information regarding the time required for surgical space formation, the operating time for gallbladder removal, the amount of intraoperation blood loss, and the occurrence of complications, such as massive intraoperation bleeding and organ damage were

Table 1
Use of the LOFF device in GLESP cholecystectomy.

	1	2	3	4	5
Body weight (kg)	64.6	63.2	65.1	65.8	63.5
Surgical method switch during operation	No	No	2-hole	No	No
Intraoperative blood loss (ml)	25	20	85	12	10
T1 (min)	10	8	5	5	5
T2 (min)	63	40	40	25	21

Notes: T1 is the time for operative field formation; T2 is the operating time for gallbladder removal.

measured (Tables 1 and 2).

2.8. Statistics

SPSS 16.0 software was used for statistical analysis. The measurement data are expressed as (x±SD). The enumeration data were tested using $\chi 2$ tests, and the normally distributed measurement data were tested using T-tests. A P value less than 0.05 indicated that the difference was statistically significant.

3. Results

3.1. Compression of and damage to organs by the LOFF device

In all experimental animals, the LOFF device successfully formed the surgical space and maintained the space for more than 2 h. Additionally, 2 h of placement of the LOFF device in the abdominal cavity did not result in a significantly different degree of damage to the surrounding organs such as the small intestine, stomach, liver and omenta (Fig. 2).

3.2. Evaluation of the LOFF-LESS surgery in animals

The LOFF-LESS surgeries of five pigs were performed by the same group of doctors all trained, mentored and supervised by Dr. Hai Hu. The animals' vital signs were stable during the surgery, and all of the animals recovered from anaesthesia 30 min after surgery. Macroscopically, the intraoperation observation revealed no noticeable organ adhesion or injury in the abdominal cavity, and the gallbladder had clear boundaries without any pathological changes such as gallbladder stones or inflammation. Four operations were completed smoothly. However, one was switched to two ports surgery with an additional incision below the xiphoid process because of intra-operative blood loss.

3.3. Comparison of LESS, GLESP and LOFF-LESS surgeries in animals

The laparaendoscopic cholecystectomies of nine pigs were performed by the same group of doctors. The surgeries of the three groups were all completed smoothly. No significant difference was found in the length of incision among the LESS, LOFF-LESS and GLESP groups. Calot's triangle was exposed the most clearly without any lifting in the LOFF-LESS group. With lifting using separating pliers, the same level of exposure could be achieved in the LESS and GLESP groups. The exposure of Calot's triangle was the poorest in the GLESP group among the three groups (Fig. 3). Our results demonstrated that compared with the control (tissues from the animals that received pneumoperitoneum-aided laparoscopic surgery), the experimental group exhibited slightly increased vascular congestion in the omenta and insignificantly different vascular congestion in the serosal, muscular, and mucosal layers of the small intestine, stomach, liver, and colon as indicated by hematoxylin and eosin (HE) staining (Fig. 3). The use of the LOFF device in GLESP cholecystectomy was first evaluated (Table 1). Moreover, the time for surgical space formation (4.4 ± 1.2 and 4.8 ± 1.0), the operating time for gallbladder removal (25.2 ± 4.8 and 25.4 ± 2.7), and the loss of blood (9.4 ± 3.1and 9.2 ± 2.4) was similar between LESS and LOFF, respectively (Table 2). In contrast these parameters were higher in GLESP (6.6 ± 1.0, 30.3 ± 4.4 and 10.1 ± 2.0, respectively. No differences were found in intraoperative complications (Table 2).

Table 2
Comparison of the observation parameters among the three groups.

	LESS	GLESP	LOFF	P value
Number of study subjects	3	3	3	–
T1 (min)	4.4 ± 1.2	6.6 ± 1.0	4.8 ± 1.0	0.09
T2 (min)	25.2 ± 4.8	30.3 ± 4.4	25.4 ± 2.7	0.29
Amount of blood loss (ml)	9.4 ± 3.1	10.1 ± 2.0	9.2 ± 2.4	0.90
Intraoperative complications	0	0	0	–

Notes: T1 is the time for surgical space formation; T2 is the operating time for gallbladder removal.

4. Discussion

Since the performance of the first laparaendoscopic cholecystectomy in France in 1987, this surgical technique has advanced rapidly because of its distinctive advantages. Among these, the risk of bleeding during surgery is reduced due to the small size of the incision, as well as reducing the risk of pain or bleeding after the surgery. Moreover, after laparaendoscopy the risk of post-operative infection and the length of hospital stay is much shorter than after open surgery. However, accumulating clinical data have also directed the attention of researchers and doctors to the dangers of pneumoperitoneum [9]. When pneumoperitoneum is used, CO_2 can enter the circulatory system through the peritoneum, abdominal organs, and broken vessels, resulting in adverse effects on the circulatory system [1], the respiratory system [2], blood coagulation [10], and the nervous system [11] as well as increasing the risk of maternal-foetal hypoxia [3] and the risk of seeding of free tumour cells in the abdominal cavity [4]. Therefore, although traditional surgical approaches continue to be applied and promoted in clinical practice, new gasless laparaendoscopic techniques have emerged. Between 1991 and 1992, Nagai, Hayakawn, and Kitano et al. [12,13] in Japan led their groups to conduct gasless laparaendoscopic cholecystectomy and stone removal through the opened common bile duct using stainless steel strips and U-shaped retractors. Kurt Semm in Germanyand Cazayerli in the United States used a 'T-shaped' fan-like lifting device [14], Mouret in France [5] used a spiral lifting device, and Maher in Australia [15] used a 'cloth hanger'-like lifting device in combination with pneumoperitoneum for low-pressure pneumoperitoneum-aided laparaendoscopic surgery in gynaecology. Despite the increasing application and development of gasless laparaendoscopic techniques in clinic practice, these techniques also have the following drawbacks: (l) lifting the anterior abdominal wall without insufficient forces on the omenta and intestine will cause the intestine to move towards the middle thereby blocking the operation field particularly in obese patients; and (2) the mechanical arms occupy space above the abdominal wall, constraining the range of operating movement to a certain extent. Limited by the above problems, the development of devices for gasless surgeries has not made any major advances since 2000, which in turn has affected the promotion and development of gasless surgeries [8]. Aiming to overcome the shortcoming of poor operation field exposure in gasless laparaendoscopic surgery, we developed a LOFF platform after four years of effort. Here, we report for the first time the outcomes of LOFF-LESS surgery, specifically related to safety and effectiveness of this platform as verified by our experiments using an animal model.

As mentioned in the Methods section, in order to develop an ideal LOFF device, we tested six prototypes with different shapes: a rigid wide sheet, a wire-like shape with a flexible base, a flexible wire-like shape, a hollow conical shape, a hollow cylindrical shape, and a hollow triangular prismatic shape (Fig. 4). However, the hollow triangular prismatic device resulted in superior exposure of Calot's triangle in the upper abdominal cavity. An air pressure of approximately 80 kPa is required to retain the formed shape of the LOFF device inserted into the abdominal cavity. Excessively high pressure could result in explosion of the supporting balloon, and

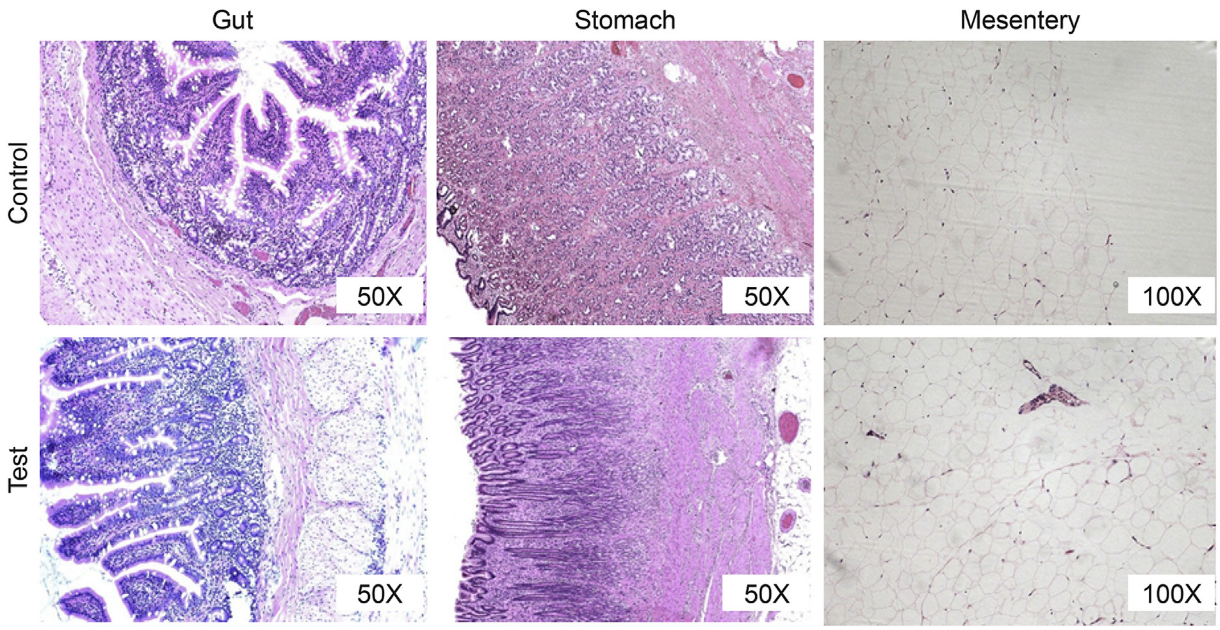

Fig. 2. Compression and damage to surrounding organs caused by the LOFF device. Samples of the tissues that contacted the LOFF device were analysed after HE staining. 'Control' denotes tissues harvested from the intestine, stomach, and omenta after pneumoperitoneum-aided LESS surgery; 'Test' denotes tissues harvested from the intestine, stomach, and omenta after LOFF-LESS surgery. There are no detectable differences between 'Control' and 'Test'.

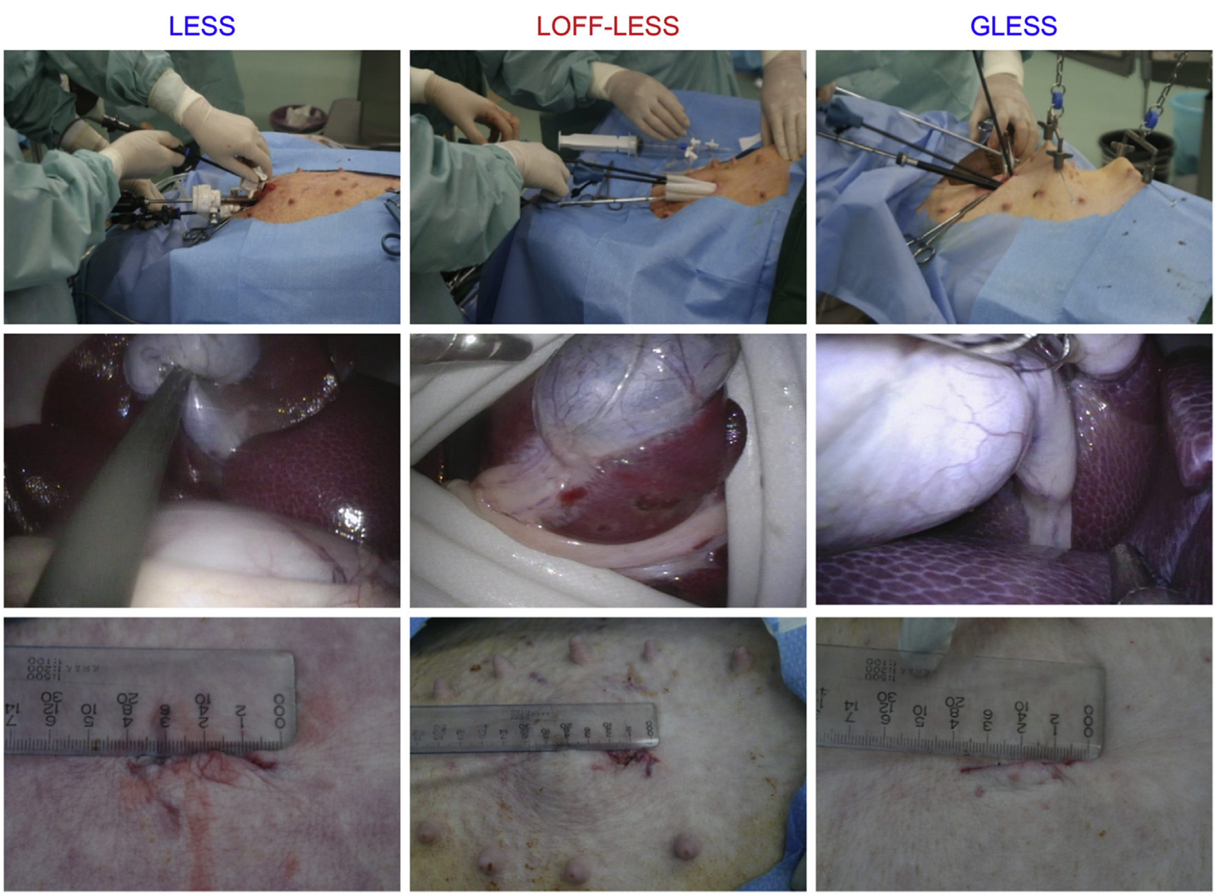

Fig. 3. Comparison of the incisions and operation fields among the LESS, LOFF-LESS, and GLESP groups. There was no significant difference in the length of incision among the LESS, LOFF-LESS and GLESP groups. Calot's triangle was exposed the most clearly without any lifting in the LOFF-LESS group. With lifting using separating pliers, the same level of exposure could be achieved in the LESS and GLESP groups. The exposure of Calot's triangle was the poorest in the GLESP group among the three groups.

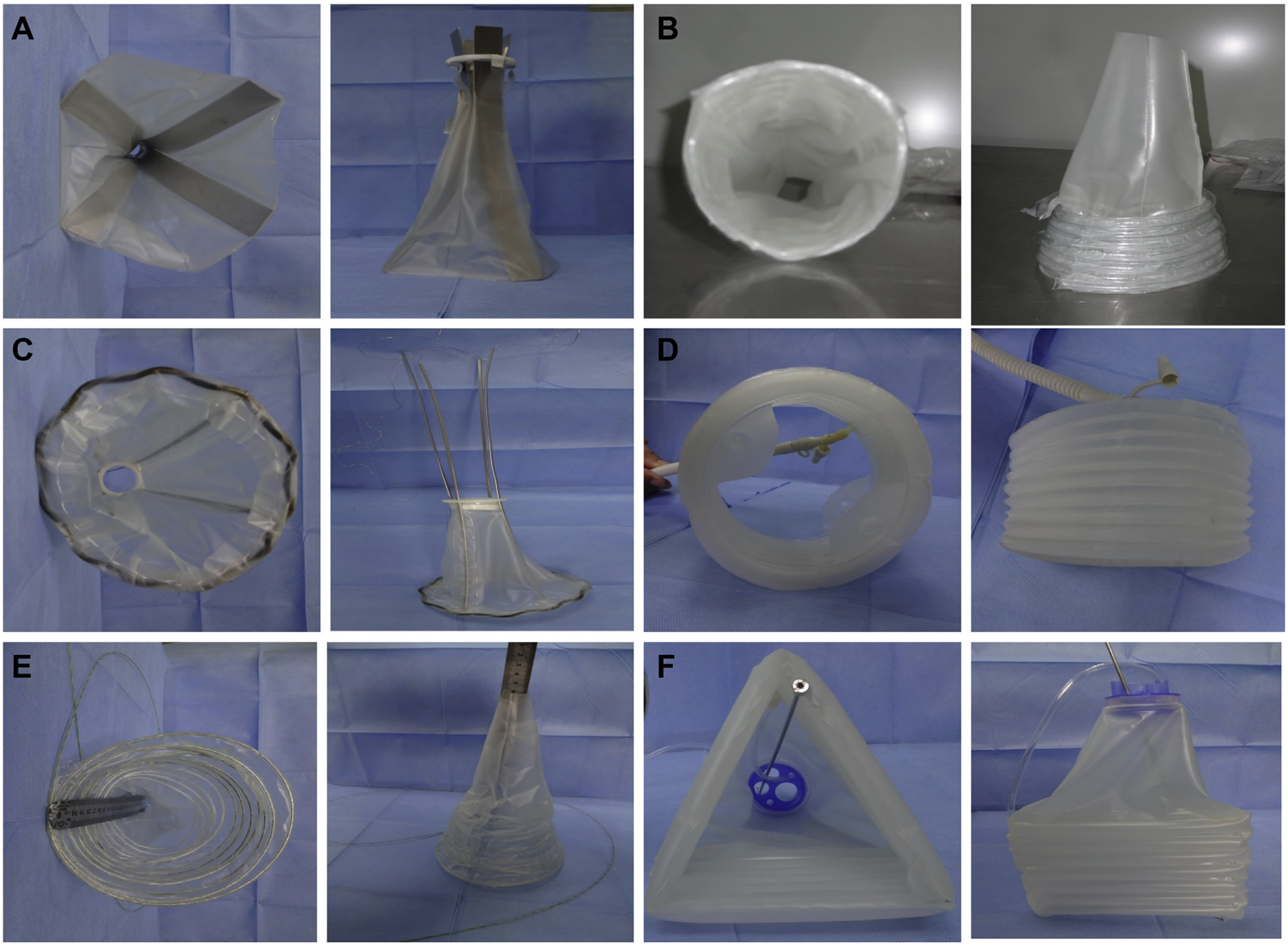

Fig. 4. Six types of LOFF devices. In the animals tested, the first four devices (A, B, C, D) either could not form a surgical space in the abdominal cavity or could only form a surgical space that offered very poor visibility. The hollow cylindrical (E) and hollow triangular prismatic (F) devices successfully formed a surgical space after inflation. Compared with the hollow cylindrical device (E), the hollow triangular prismatic device (F) resulted in superior exposure of Calot's triangle in the upper abdominal cavity. If the muscle tonus in the abdominal muscles was high, the inflated hollow cylindrical device (E) became oval, producing poor exposure of Calot's triangle. This shortcoming was more evident in patients without gastrointestinal decompression. However, the hollow cylindrical device was greatly advantageous for exposing the pelvic organs because the adequate space in the lower abdominal cavity allowed the device to retain its normal round shape after inflation.

excessively low pressure leads to formation insufficiency resulting in poor visibility of the surgical field. The inflated LOFF device pushes against and compresses the surrounding organs, including the small intestine, stomach, liver, and transverse colon. To investigate compression-induced damage to the surrounding organs by the LOFF device, we maintained the shape of the balloon for 2 h and then harvested tissue samples from the compressed organs for pathological examination after removal of the device. Our results suggest that the use of LOFF devices in the body is safe and feasible.

The LOFF device was used for LOFF-LESS surgery in five pigs with an average operating time of 30 min. Four of these operations were completed smoothly within 25–30 min, and one required a longer time, indicating the feasibility of LOFF-LESS surgery. In all of the operations, the exposure of Calot's triangle was satisfactory, and the pig remained in a supine position without the necessity for position change. One reason for this is that the top edge of the triangular prismatic supporting part can support the anterior abdominal wall, the medial edge is located near the hepatoduodenal ligament, and the lateral edge is located near the hepatocolic ligament, whereas the bottom surface is on top of the transverse colon and duodenum. Through such a placement, the duodenum and transverse colon can be pushed away from the gallbladder, whereas the hepatoduodenal ligament is pushed leftward in the abdominal cavity by the medial edge of the supporting part. Consequently, when the operator pulls the gallbladder towards the upper right, the curved bile duct can be easily pulled straight; furthermore, the thin membrane of the supporting body prevents movement of the omenta and intestine surrounding the gallbladder, resulting in the convenient and clear exposure of Calot's triangle.

Despite the various advantages of the LOFF device, it nonetheless suffers one of the problems shared by all single-site endoscopic technologies, i.e., difficulty in placing the surgical tools into a triangular area and the inconvenience of a crowded surgical space with an insufficient 'straight-line' operation field. In addition, preoperation exploration of the abdominal cavity when using a LOFF platform is not as convenient as in the LESS surgery without the aid of this device because the exploration requires constant position adjustment and changes in inflation and deflation of the device.

5. Conclusions

In summary, the LOFF-LESS technology is safe, effective, and feasible. The technology eliminates the risks of pneumoperitoneum-associated complications while maintaining the advantages of LESS technology, including less postoperation pain, fast recovery, and extremely high cosmetic satisfaction. More studies are required but there is promise in using this procedure in a clinical setting in the future. In addition, we will consider further specialisation of this technology, e.g., the use of the LOFF device in gastrointestinal surgery, obstetrics and gynaecology, and hernia surgery, thus further expanding the advantages of gasless laparaendoscopic surgery. Altogether, the experimental results in animals confirmed the feasibility, superiority, and high cosmetic satisfaction of this operation platform. The invention of this device can shed new light on further development of gasless laparaendoscopic surgery.

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Authors contribution

Drs. Hai Hu drafted the article and revised it critically for important intellectual content, Kai Zhang, Gang Zhao, Zhaoyan Jiang, Anhua Huang, contributed to the conception and design of the study, or acquisition of data, Jingli Cai, Anan Xu, Haidong Li, Chuanqi He, Kan Ding and Ruiqi Lu acquired data and revised critically the manuscript.

Conflicts of interest

The authors declare that they have no conflicts of interest or financial ties to disclose.

Guarantor

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Appendix A. Supplementary data

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.amsu.2016.11.010.

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