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Animal Validation of a New Single-Incision Device for Flexible-Single-Incision-Surgery

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Abstract

Background: A new single-port device (FSIS-Flexible-Single-Incision-Surgery) is presented. This new platform has three working channels, two for rigid instruments and one for the flexible endoscope. The channel for flexible instruments offers a pneumatic sealing to avoid the air's leak of the cavity (abdomen, rectum, and vagina). In this study the preclinical data are shown testing the feasibility and safety for laparo-endoscopic instruments.

Methods: Experimental evaluation of feasibility and safety in two stages. In the first stage a working channel with pneumatic sealing was tested in simulators to use a flexible endoscope. In the second stage (animal model) the single incision device that makes possible to use laparoscopic instruments and flexible endoscopes was tested. The measured variables were: time of the procedure, CO_2 employed, adverse intraoperative events, grip's losing, losing of pneumatic sealing, feasibility and safety of the procedure for the surgeon.

Results: The hysterectomy and double adnexectomy was done with a median time of 7.1 minutes. The median of the CO_2 consumption was 32.5 litres. Only in one case (16.6%) the surgeon had problems with the abdominal navigation of the endoscope that was easily solved. The grip's lose wasn't a major problem. The median size of the skin incision was 5.4 cm. The median surgeon' score for the feasibility was 10 and for the safety were 9.6.

Conclusion: The surgeons considered that the use of the device was very feasible and safe. The FSIS-device is a universal platform for Single-Incision-Surgery for surgeons and gastroenterologists and for abdominal, rectal and vaginal access.

Keywords: Endoscopic surgery; Laparoscopy; Flexible endoscopy; Single-incision-surgery; Surgical simulation; Experimental

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Introduction

NOTES (Natural Orifice Transluminal Endoscopic Surgery) was developed with a desire to increase the benefits of Minimally Invasive Surgery and to produce a minor trauma to the abdominal wall. This Surgery "without scars" should be able to avoid or minimize as much as possible the main problems on Laparoscopic Surgery (surgical wound infection, adhesions, post-operational pain, ventral hernias, etc.). At the beginning, it was a combined surgery that used the knowledge of laparoscopic surgery to reproduce the intraperitoneal surgery technique, and the knowledge on flexible endoscope to access to the abdominal cavity through natural orifices as the mouth, the vagina, the anus or the urethra. The first description was made by Kallo in 2004 when he successfully performed a trans gastric peritoneoscopy and a liver biopsy on a porcine model [1]. The clinical application arrives at the early 2007. The Zorron's team performed the first series of NOTES transvaginal cholecystectomies on four patients [2,3]. Shortly after, Bessler performed a successfully hybrid transvaginal cholecystectomy with 3 laparoscopic abdominal ports [4]. Marescaux, on April 2007, performed a clearer NOTES cholecystectomy, using just one abdominal gate to introduce a Veress needle, to control the pneumoperitoneum [5]. The first hybrid transvaginal NOTES cholecystectomy in Spain was performed by Noguera's team, on October 2007 and the first transgastric NOTES cholecystectomy was carried up by Lacy on November 2007 [6,7]. The development of these different approaches has been rather uneven. The transgastric approach was the pioneer; it was the starting point of the NOTES development, with the first transgastric abdominal explorations. It soon faces problems difficult to be solved: the way to open and close

the gastrostomy, the impossibility to work in parallel with additional laparoscopic instruments or the difficulty to act effectively and safety if complications arise. The transvaginal approach is the most successful since NOTES development starts till nowadays. It was the first to be applied in clinical practice safely. The high and fast translation into practice it was due to the well-known safety in the transvaginal approach from the posterior fornix, and the easy way to access and to close the colpotomy. Based on the last progress and developments on endoscopic surgery, a "fusion surgery" has been developed applying the previous experience with the flexible endoscope and new approaches through the umbilicus in a single-incision surgery, "Flexible Single Incision Surgery (FSIS)". This experience was published by Noguera on 2013, showing that this new approach has several advantages and it allows developing NOTES surgery through the navel [8]. On the other hand, it is necessary to have prior experience with the use of the flexible endoscope used for surgical gestures and to have a device to solve the problems derived from using a flexible endoscope through a single port device for rigid instruments. Currently, this technique needs new surgical devices adapted to flexible endoscopic platforms, the future platforms in endoscopic surgery. These single-port devices look for a new philosophy and redesign that makes possible the operation using both rigid instruments and flexible endoscopy platforms. We present a new single-port device called FSIS device (Flexible-Single-Incision-Surgery) because we can introduce through the working channels rigid instruments, rigidoptics and flexible endoscopes (with internal working channels). This new platform has three working channels, two for rigid instruments from 5 mm to 12 mm wide and one channel for the flexible endoscope or rigid optic. The channel for flexible instruments offers a pneumatic sealing to avoid the leak of the air of the cavity (abdomen, rectum, and vagina) and allows introducing the flexible endoscope without the risk to damage it and offering a good endoscope's mobilization. In this study we show the preclinical data in order to implement the use of the device in humans. The FSIS device may be a good option to improve and to increase the endoscopic rectal resections offering the endoscopist a good exposition and good tissue coagulation. It may improve the trans rectal procedures as the EMR (Endoscopic Mucosal Resection) and ESD (Endoscopic Submucosal Dissection) and the transanal procedures made by surgeons with the possibility to navigate with a flexible endoscope. The aim of the study is to present the feasibility, safety and efficacy of a new single incision device for laparoscopic and flexible endoscopic instruments in a pre-clinical evaluation.

Materials and Methods

The prototype of the (Flexible Single Incision Surgery) FSIS was created in two well-differentiated stages. In the first stage a working channel with pneumatic sealing was created to be able to use a flexible endoscope through a short surgical trocar. In the second stage this validated working channel with pneumatic sealing was inserted in a single incision device. This device is a surgical platform with three working channels that makes possible to use laparoscopic instruments and flexible endoscopes working together. The experimental validation was made at the Centro Tecnológico de Formación de A Coruña (CTF). This experimental laboratory has a long tradition in surgical training and investigations and the possibility to perform validations of surgical instruments in simulators and animal models. For the first validation of the single channel with pneumatic sealing a simulation model was used. A lap-training box was employed and the working channel was fixed in its cover. The feasibility of the introduction of the flexible endoscope, the possibility to work whit the flexible endoscope and the freedom of movements were achieved in 6 investigations. In the second validation the FSIS device with the three working channels was tested. In 6 new investigations in lap-training box the feasibility of working together laparoscopic instruments and the flexible endoscope were evaluated. After this evaluation in simulators the FSIS device was tested in an animal model. Six female White Large pigs between 20 kg to 25 kg were operated. The experimental procedure was authorised by the Ethical Committee for animal welfare and good laboratory practices. The surgical intervention was done under general anaesthesia and a midline approach of 5 cm was created in the pig in the middle of the xipho-pubic line. The FSIS device was inserted and three surgical stitches fixed it to the abdominal wall. The pneumoperitoneum was used at 12 mmHg and the surgical procedure planned was a subtotal hysterectomy with bilateral adnexectomy. Every prototype of the device was employed for two experimental procedures. The intervention was performed with a flexible gastro scope with single working channel (video gastro scope GIF-FQ260Z™, Olympus) through the working channel with pneumatic sealing and two laparoscopic rigid instruments. The straight rigid instruments were a 5 mm articulating clincher (SILSClinch36™, Covidien-Medtronic) and a 5 mm tissue-sealer (Ligasure™ Maryland Jaw 37 cm, Covidien-Medtronic). The Pneumo peritoneum was maintained by the internal channel of the device and the pneumatic sealing of the main working channel was maintained by an independent channel for the introduction of air with a syringe. The vision and illumination was offered by the flexible endoscope. The straight grasper was used for the traction of the specimen and the Ligature for the tissue and vessel sealing. The number of tries to grip with the laparoscopic grasper in the subtotal histerectomy and bilateral adnexectomy was 5 per animal (2 in each adnexe and 1 in the main and upper part of the common uterus). The 2.4 mm flexible grasper through the flexible endoscope (Rescue™ alligator grasping forcep, Boston Scientifics) was only used to catch the surgical specimen for extraction. The procedure was done by two surgeons, one with the flexible endoscope and the other with the laparoscopic instruments (Figure 1). The specimen was tested for its integrity (Figure 2). The laparoscopic tower employed was a double vision Olympus system (Evis Exera II, CV-180 video system, Olympus) with a connection for the flexible endoscope and another for the laparoscope. The surgical procedures were recorded by a laparoscopic 10 mm optic introduced in the left side of the abdominal wall through an 11 mm trocar. The only use of this entry-port was to record the procedure in order to do a later analysis of the movements. The simulation and animal procedures were always performed by the same three investigators with a wide experience in single-incision surgery and the use of the flexible endoscope. In the procedure were recorded this surgical variables: time of the procedure, CO_2 employed in the procedure (to evaluate the leak of CO_2), adverse intraoperative events (haemorrhage, visceral lesion, others), number of grip's losing of the straights and flexible graspers, number of losing of pneumatic sealing in the working channel for the endoscope, feasibility of the procedure for the surgeon (VAS 0 to 10 score) and safety of the procedure for the surgeon (VAS 0 to 10 score). The experimental procedure didn't need animal survival and finished when the surgical interventions were performed. All the animals were used after the intervention for the surgical training of the surgical residents as usual.

Results

The first evaluation was made to achieve the correct pneumatic

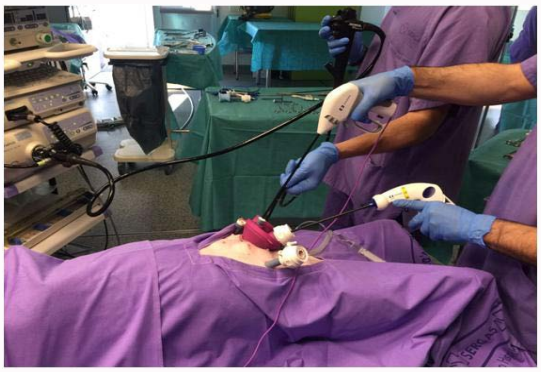

Figure 1: Flexible-single-incision-device being manipulated by two surgeons. One with the flexible endoscope and the other with the 5-mm grasper and the tissue-sealer. It is notorious the freedom of movements of each surgeon.

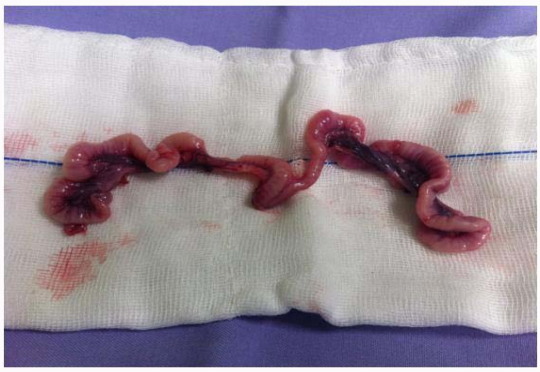

Figure 2: Surgical specimen in the female pig: subtotal histerectomy and bilateral adnexectomy.

sealing of the main working channel of the device. It was performed in lap-training box with the flexible endoscope in 6 experimental procedures. In this evaluation there was no problem to seal the pneumatic system around the endoscope and to handle it with the same options that in the use without a working channel. In the second evaluation the FSIS device was tested. The aim in this case was to know if the pneumatic sealing and the freedom of movements for the endoscope were the same in the device that in the single working channel. Six new experimental procedures were realized in the lap-training box without any problem in neither pneumatic sealing nor the mobility of the endoscope. The third evaluation was performed in 6 pigs with the FSIS device. This *in vivo* test had a median time of procedure of 7.1 minutes (range 5 to 8.8). This was the time for the surgical procedure excluding the introduction of the device. The global procedure (device insertion and surgical procedure) was 12.3 minutes (range 9.2 to 13.9). The leak of pneumoperitoneum in the abdominal cavity was tested with the consumption of CO_2 by the insufflators. The median of the CO_2 consumption was 32.5 litres (range 11 to 70). In the six procedures there were four of them without any leak (11, 14, 16 and 21 litres, median 15.5 litres) and two procedures with CO_2 leak (65 and 70 litres) located at the insertion of the device in the abdominal wall of the pig. The leak in the pneumatic sealing at the working channel for the flexible endoscope was null. In relation to the adverse intraoperative events we found three problems in the six procedures (50%). Two of them were the previously commented leak of CO_2 (33.3%), partially solved with a surgical skin's suture around the device and only in one case (16.6%) the first assistant had problems with the abdominal navigation of the endoscope that was partially solved with a Trendelenburg forced position of the animal. The grip's lose with the laparoscopic grasper may occur when we work with a single-incision device. Using the FSIS device we lost the bite of the laparoscopic 5 mm grasper in 7 cases from 30 (23.3%) and in 0 cases with the flexible grasper employed to extract the specimen. The resected specimen was complete and without problems of parietal integrity in all cases. Median size of the skin incision was 5.4 cm (range 5 to 6). In 2 cases the skin incision was bigger than needed causing the two cases with leaks of CO_2 around the device. At the final of the procedure the surgeon and first assistant performed an evaluation of the feasibility and safety of the procedure in a 0 to 10 VAS score. The median score for the feasibility was 10 (range 10 to 10) and for the safety was 9.6 (range 8 to 10).

Discussion

The aim of the invention is to offer a single-incision device for laparo-endoscopic surgery with the possibility to use the flexible endoscope. It is a medical device for endoscopic surgery that solves a problem: the use of flexible endoscopes through a conventional trocar or device for single incision access. Nowadays the trocars and devices don't allow working with the flexible endoscope due to problems with the endoscope's movements and the possibility to damage the endoscope in its flexible part. The FSIS-device is adaptable for abdominal surgery entering through the umbilicus or other abdominal part and for a rectal and vaginal approach too. The new surgical device offers the possibility to work through a single incision multichannel device with rigid and flexible instruments. It allows us to work with the flexible endoscope avoiding the damage to the endoscope and offering a complete freedom of movements for the flexible endoscope without leaks of the air or CO_2 used for the creation of the virtual space (pneumoperitoneum, pneumorectum or pneumovagina). The FSIS-device is the unique single-port multichannel device to work with flexible endoscopes and the first and unique working channel with a pneumatic-pad sealing. In the simulator and animal validation the FSIS-device had very satisfactory results. The main potential problem, the CO_2 or air's leak, was successfully solved by the engineers in the main working channel when it was employed only or integrated in the device with the other channels for laparoscopic instruments. The leaks of CO_2 around the device were a minor problem due to the lack of elasticity of the prototype, to be solved in a subsequent commercial model. In the experience of the training programme we consider there is a cut-point of 25 litres to consider there is an air leak in a procedure with duration less than 15 minutes (data not published). In our experimental series there were two cases with air leaks but the problem was located in the insertion of the device and nor in the device. The duration of the surgical procedure was similar when we used the FSIS-device than when we used a common laparoscopic approach. The median of 7.1 minutes is a good parameter for this procedure. The only comparator for this procedure we have is the median of 10 minutes in the training programme of the surgical residents. In relation to the adverse events the only problem we had was the difficulty to navigate with the flexible endoscope in one case. The investigators have experience in using the flexible endoscope due to the training programme and the clinical experience in NOTES-procedures [8,9]. In the aforementioned case there was a great dilatation of the small bowel that hind to reach the pelvis in the pig. It was easily solved by forcing the animal's position. Some surgeons have problems to have a good grasping and traction in the single-incision-surgery due to the conflict of space to move the hands and instruments. In this device we have evaluated the number

of grip's losing as an objective parameter to check it. We consider 23% of failing grips is a good parameter in this kind of approach although we don't have any data about this problem in the clinical use. The incision made to insert the device is probably bigger than for other devices but smaller than the assistance laparotomy in a colorectal laparoscopic procedure. The device has an appropriate external diameter to be used in a transanal or transvaginal approach, similar to the commercial ones employed nowadays for transanal procedures. The global evaluation of the procedure using the FSIS-device was very encouraging. The surgeons considered that the use of the device was very feasibly and safe and they will have not ethical conflicts to use it in a clinical series. The FSIS-device is a universal platform for Single-Incision-Surgery for surgeons and gastroenterologists and for abdominal, rectal and vaginal access. This new device offers the possibility to introduce a new "fusion surgery" with the rigid and flexible instruments and it is adapted to flexible endoscopic platforms, the future platforms in endoscopic surgery. It may be used by endoscopic surgeons, therapeutic gastroenterologists, gynaecologists, urologists, Clinical series that reproduce the feasibility and safety of the device's use must be developed. The transanal use of the FSIS-device may be a great advance to perform endoscopic mucosal resection, submucosal dissection and full-thickness resection in rectal tumors. These procedures will be made faster and safer than with the isolated use of the flexible endoscope.

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Author Disclosures

Dr. Noguera reports personal fees from Medtronic, other from Johnson & Johnson, outside the submitted work. Dr. Aguirrezabalaga reports other from Medtronic and Johnson & Johnson, outside the submitted work. Dr. Noguera, Dr. Aguirrezabalaga and Dr. Centeno report: In addition they have a pending patent (EP17382349).G. Fernandez has nothing to disclose.

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