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Case Series of the Month

SPIDER Surgical System for Urologic Procedures With Laparoendoscopic Single-Site Surgery: From Initial Laboratory Experience to First Clinical Application

Georges-Pascal Haber^{1,*}, *Riccardo Autorino*¹, *Humberto Laydner*, *Bo Yang*,
Michael A. White, *Shahab Hillyer*, *Fatih Altunrende*, *Rakesh Khanna*, *Gregory Spana*,
Isac Wahib, *Khaled Fareed*, *Robert J. Stein*, *Jihad H. Kaouk*

Section of Laparoscopic and Robotic Surgery, Glickman Urological and Kidney Institute, Cleveland Clinic, Cleveland, OH, USA

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Abstract

This case study describes our initial laboratory experience using the SPIDER surgical system (TransEnterix, Morrisville, NC, USA) for laparoendoscopic single-site surgery (LESS) urologic procedures and reports its first clinical application. The SPIDER system was tested in a laboratory setting and used for a clinical case of renal cyst decortication. Three tasks were performed during the dry lab session, and different urologic procedures were conducted in a porcine model. The time to complete the tasks and penalties were registered during the dry lab session. Perioperative outcomes and subjective assessment by the surgeons were registered.

The surgeons had a positive experience with the SPIDER system, with a mean overall score of 3.6 (on a scale of 1–5). The surgeons were able to gain proficiency in performing tasks regardless of their level of expertise. The highest scores recorded were for ease of device insertion, instrument insertion and exchange, and triangulation. The lowest scores were for retraction. During the clinical case, the platform provided good triangulation without instrument clashing. However, retraction was challenging because of the lack of strength and precise maneuverability with the tip of the instruments fully deployed. The SPIDER system offers intuitive instrument maneuverability and restored triangulation without external instrument clashing. Further refinements are awaited to define its role in the urologic LESS armamentarium.

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¹ These authors contributed equally.

* Corresponding author. Section of Laparoscopic and Robotic Surgery, Glickman Urological and Kidney Institute, Cleveland Clinic, 9500 Euclid Avenue, Cleveland, OH 44195, USA.
E-mail address: haberg2@ccf.org (G.-P. Haber).

1. Case series

Early comparative studies have suggested that laparoendoscopic single-site surgery (LESS) is not inferior to laparos-

copy in terms of perioperative outcomes and has the potential advantage of reduced surgical trauma [1,2]. To overcome technical limitations related to ergonomics during LESS, new-generation purpose-built platforms and

instruments are being developed [3]. Moreover, the application of robotic technology is being proposed to further minimize the limitations of LESS [4,5].

Current instrumentation still fails to provide the surgeon with the optimal ergonomics for ideal visual orientation and tissue manipulation. Thus, a system that might effectively replicate multiport laparoscopy by enabling ideal triangulation and maintaining effective retraction capabilities has yet to be defined. The SPIDER surgical system (TransEnterix, Morrisville, NC, USA) is a novel technology that has been reported to be safe and effective for LESS cholecystectomy in animal model [6]. The US Food and Drug Administration recently cleared the first-generation system for use in a range of abdominal procedures, even if its clinical use has not yet been reported. The aim of this study was to describe initial laboratory experience using the SPIDER platform for LESS urologic procedures and to report its first clinical application.

1.1. Laboratory evaluation

The SPIDER system was tested in both dry and wet laboratory settings. Surgeons with different levels of expertise were involved, none having previously used this platform. The platform allows surgeons to advance and manipulate multiple surgical instruments through a single port/cannula (outer diameter: 18 mm) encapsulating four working channels (two flexible and two rigid; Fig. 1). When the SPIDER system has been advanced into the abdominal cavity, flexible instrument delivery tubes (IDTs) are deployed and used to guide flexible surgical instruments. For the experimental part of the study, a second-generation SPIDER platform was used (Fig. 2).

For the dry lab, three tasks modeled after the Fundamentals of Laparoscopic Surgery (FLS) program were performed [8,9], including peg transfer, precision cutting, and suturing using intracorporeal knot tying [7] (Fig. 3). The time required for the accomplishment of each task and the number of errors were recorded (cutoff times were 300, 300, and 600 s for peg transfer, pattern cutting, and suturing, respectively) [7]. Allowable errors were (1) no drops outside the field of view for peg transfer, (2) all cuts within 2 mm of the line for the cutting task, and (3) up to a 1-mm accuracy error for the suturing task. Evaluators were blinded in terms of the performing surgeon. For the animal lab, four male pigs (30–40 kg) were used to perform variable urologic procedures requiring both extirpative and reconstructive surgical steps under general anesthesia (Fig. 4).

The insertion and setup of the SPIDER system were assessed. Intraoperative determinations were based on operative time, time to manage the pedicle, warm ischemia time (WIT), suturing time, estimated blood loss (EBL), complications, and the addition of extra ports. Surgeons were asked to subjectively score performance in terms of pre-established parameters (ie, entry and exit of instruments; triangulation; dissection up, down, and laterally; retraction; precision) using a Likert-type scale.

Open access was obtained by making a 2-cm incision. The SPIDER system was inserted using the insertion trocar. A 45-cm bariatric 30° 5-mm scope (Stryker) was used. For pyeloplasty, a combination of SPIDER shears, Maryland dissector, and fenestrated grasper was used. The ureter was isolated, transected, and spatulated. Using SPIDER needle drivers, anastomosis was performed.

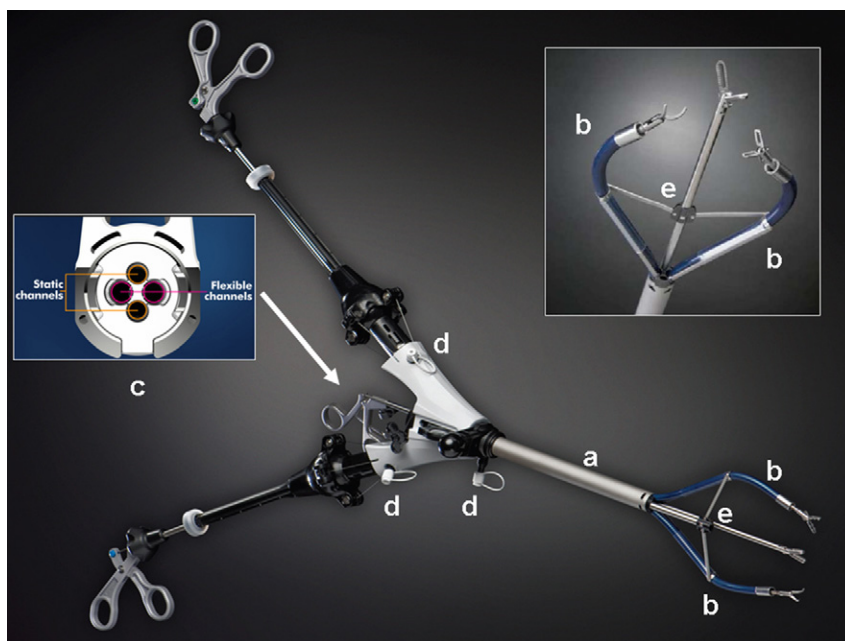


Fig. 1 – SPIDER surgical system. (a) Main body port with cannula. (b) Extended-reach instrument delivery tubes (IDTs); being flexible, the IDTs allow for *x*, *y*, and *z* motion for a multidirectional approach into and throughout the surgical field. They are actuated by a gimbal system at the proximal end that provides 360 degrees of freedom at the distal end. (c) Four working channels, two flexible and two rigid. (d) Ports for insufflation/smoke evacuation. (e) Triangulation ratchet to adjust the width of the working area. Photo courtesy of TransEnterix.

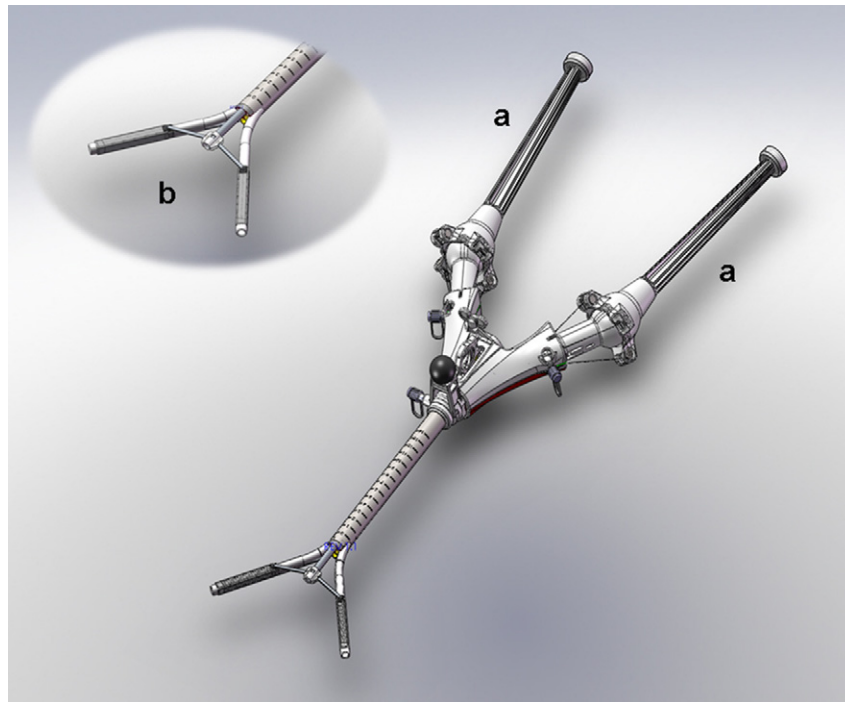


Fig. 2 – Second-generation SPIDER surgical system. (a) Redesigned instrument delivery tubes (IDTs) using a vertebral design to potentially increase the forces generated at the distal instrument tips. (b) Reduced length of the articulating portion of the IDTs to 13.4 cm. Photo courtesy of TransEnterix.

For partial nephrectomy (PN), the hilum was first dissected. The edges of the resection were scored using the SPIDER monopolar hook. Selective arterial clamping was accomplished by placing a vessel loop tourniquet. With the SPIDER suction/irrigator or fenestrated grasper on the left hand and the SPIDER shears on the right hand, a lower- or midpole PN was performed. Using SPIDER needle drivers, renorrhaphy was performed using either a “sliding-clip” technique [10] or knotless barbed sutures (2-0 V-Loc absorbable suture [Covidien, Dublin, Ireland]).

For nephrectomy, using a combination of the SPIDER monopolar hook and a Maryland dissector, the hilum was dissected. The renal artery and vein were separately clipped using the SPIDER clip applicator, and then divided. The kidney was freed and finally extracted. For partial cystectomy, the bladder dome was excised using the SPIDER wavy grasper and a monopolar hook. Closure was performed using a single layer of suture on the SPIDER needle drivers.

1.2. Clinical case

A 64-yr-old female (body mass index: 20 kg/m²) presented with a symptomatic Bosniak II left renal cyst (Fig. 5). The procedure was waived by our internal review board, and informed consent for LESS left renal cyst decortication was obtained. The procedure was performed by one surgeon of the team (GPH).

Under general anesthesia, the patient was settled in a modified flank position. Using the Hasson technique, a 2-cm umbilical incision was created. The SPIDER device was inserted into the peritoneal cavity under direct visualization

and the abdomen insufflated. Adequate field of vision was not possible because of the length of the device required inside the abdominal cavity. The SPIDER system was then reinserted through a GelPOINT port (Applied Medical, Rancho Santa Margarita, CA, USA), which provided a few centimeters to pull back the platform from the cavity into the port. The platform was placed facing the left kidney and locked in position using the docking ball. A 5-mm flexible-tip laparoscope (EndoEYE, Olympus, Orangeburg, NY, USA) was inserted through a static channel of the SPIDER platform. The cyst fluid was partially aspirated to allow a larger working space. A marionette suture was placed percutaneously to lift the cyst wall. During the different surgical steps, the SPIDER system was repositioned as needed to allow optimal working angles (Fig. 6). The cyst wall was circumferentially excised using the flexible SPIDER scissors and completed with 5-mm Endo Shears (Covidien) inserted through the GelPOINT port. After administration of indigo carmine, a collecting system opening was identified and closed with a 4-0 running suture.

Perioperative outcomes were recorded and patient satisfaction investigated through direct questioning and by administering the Patient Scar Assessment Questionnaire and Scoring System (PSAQ) [9].

2. Results

2.1. Dry lab

Mean time to complete the peg transfer task was 225.2 ± 42 s, with one registered penalty in four cases. In all

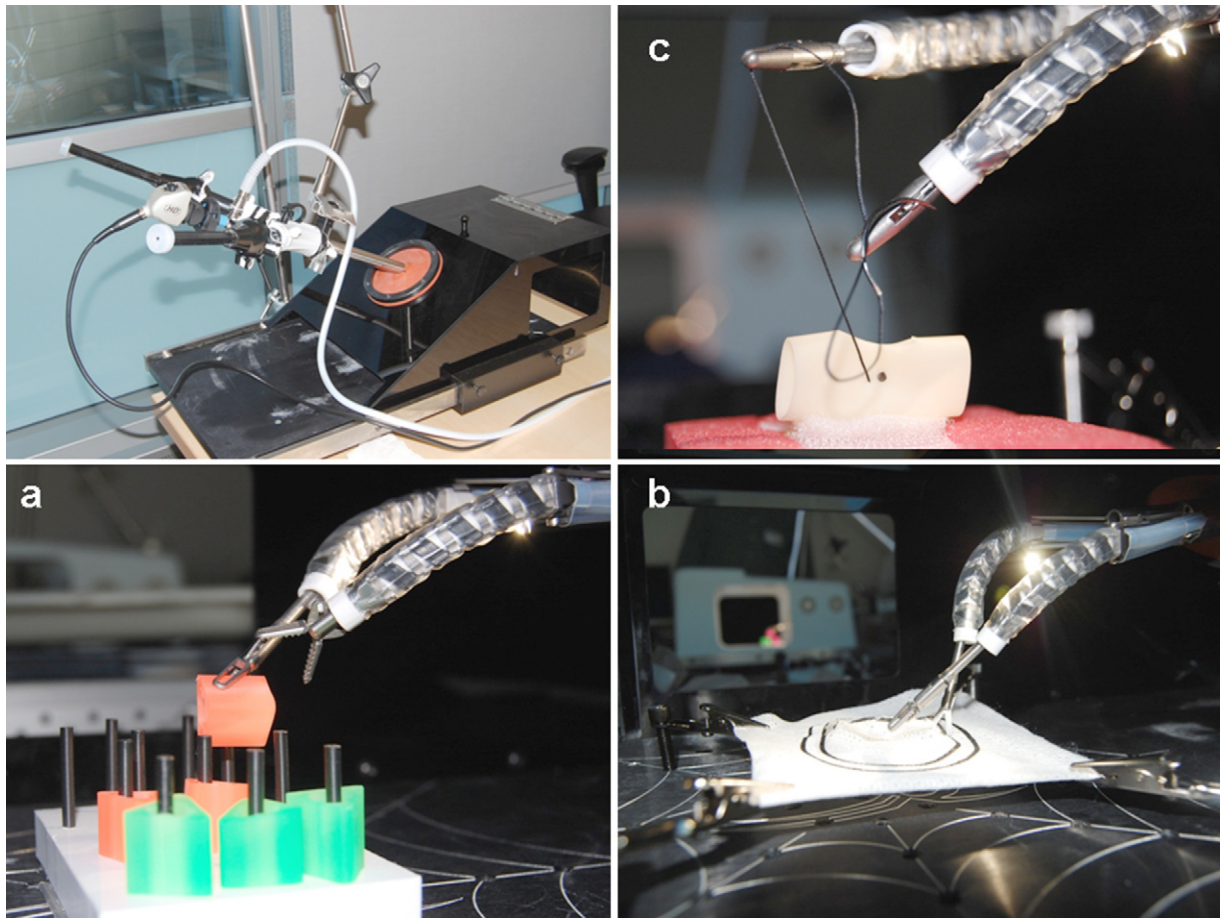


Fig. 3 – Fundamentals of Laparoscopic Surgery tasks for the dry lab. (a) Peg transfer, designed to develop depth perception and visual–spatial perception in a monocular viewing system and the coordinated use of both the dominant and nondominant hands. It also replicates the important action of transferring and positioning an object laparoscopically, as required to adjust a needle between needle holders when suturing. (b) Precision cutting teaches the concept of traction and the need to use the nondominant hand to provide a convenient working angle for the dominant hand, all within the constraints of fixed trocar positions. (c) Suturing using intracorporeal knot tying.

cases, surgeons were able to perform the task within the cutoff time limit. The mean time to complete the pattern cutting task was 245.3 ± 45.7 s, with one registered penalty in six cases. Two surgeons had two penalties, and other two had one penalty each. In all cases, surgeons were able to perform the task within the cutoff time limit. The mean time to complete the suturing task was 453.8 ± 333.6 s, with one registered penalty in six cases. One surgeon had one penalty. In this exercise, three of the surgeons were unable to complete the task within the pre-established cutoff time limit. In these cases, surgeons had a low level of expertise in LESS.

2.2. Animal lab

Overall, nine LESS surgical procedures were performed (Table 1). The mean time to set up the platform was 3 min, with no complications related to insertion. Overall mean operative time was 71 ± 21 min. For procedures requiring suturing, the mean time to complete the suture was 26 ± 6.9 min. Blood loss was negligible except for two cases of injury to the renal vein during hilar dissection. An additional 5-mm port was placed in one nephrectomy case

to control bleeding. Mean WIT for PNs was 29 min. Figure 7 summarizes the surgeons' evaluation of the SPIDER system.

2.3. Clinical case

Operative time was 180 min, with minimal EBL. Hospital stay was 36 h, and the total analgesic requirement was 26.25 mg of morphine equivalents. The visual analog scale score was 1.5 of 10 at discharge. Postoperative serum creatinine and estimated glomerular filtration rate were 0.83 and 73.6 ml/min, respectively. At 1 mo postoperatively, the patient was "satisfied" with the cosmetic result, and the PSAQ score was 51 (minimum/best score: 28; maximum/worst score: 112).

3. Discussion

Groups pioneering the LESS technique showed the clinical application of different multichannel platforms, including the TriPort (Olympus, Tokyo, Japan) [10], SILS (Covidien) [11], GelPOINT or GelPort (Applied Medical) [12,13], and X-CONE (Karl Storz, Tuttlingen, Germany) laparoscopy

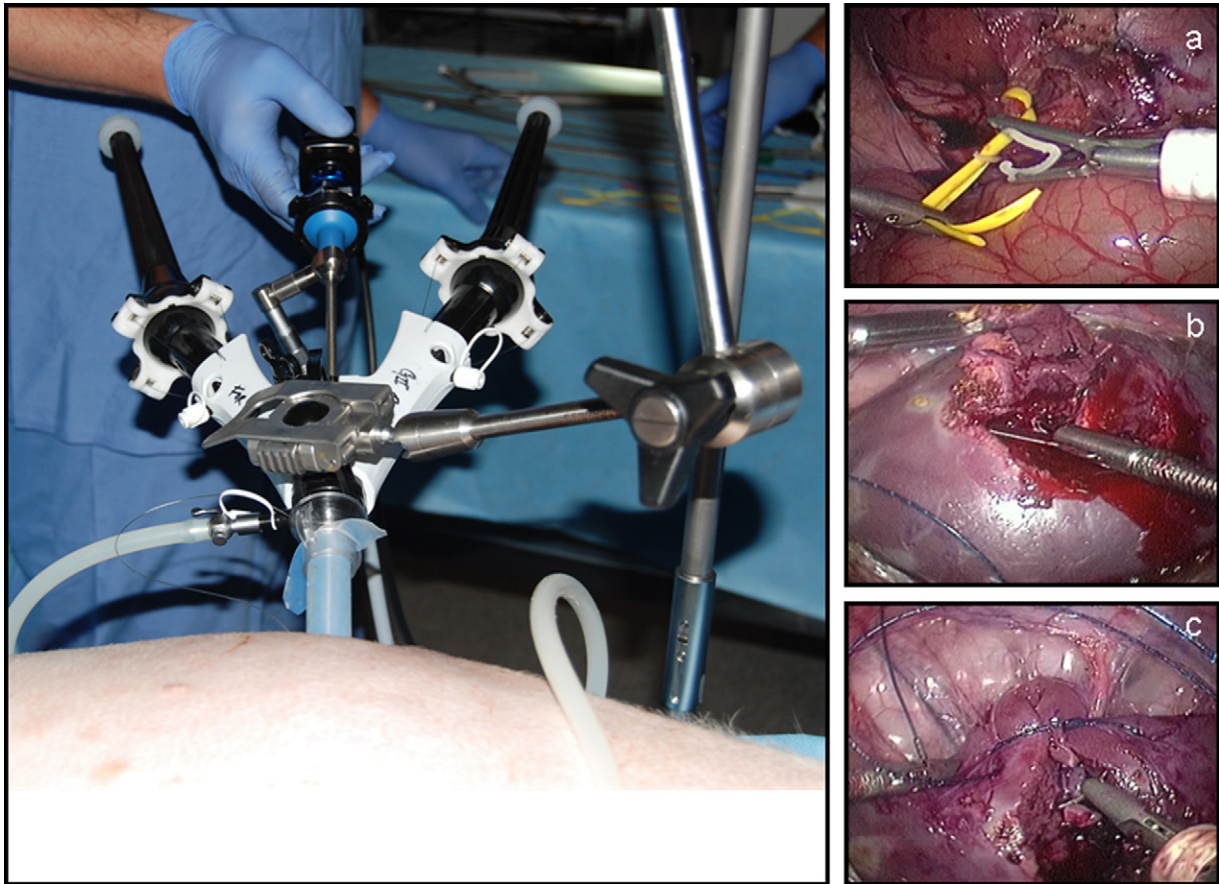


Fig. 4 – Porcine partial nephrectomy: (a) hilum management, (b) parenchymal excision, (c) knotless renorrhaphy with a barbed suture.

ports [14]. Each device presents specific features aiming to facilitate LESS. However, the ideal platform and instrumentation are yet to be defined, and optimal intraoperative ergonomics during LESS continues to be debated [4].

The SPIDER system represents an innovative surgical platform based on a novel concept designed to replicate standard laparoscopy. The system allows the surgeon to

perform different procedures using a combination of flexible and common laparoscopic instruments. Pryor et al demonstrated the feasibility of LESS cholecystectomy in a porcine model by using the first-generation SPIDER system [7], which is currently available on the US market. We performed a case of renal cyst decortication using this same system. To our knowledge, our experience represents

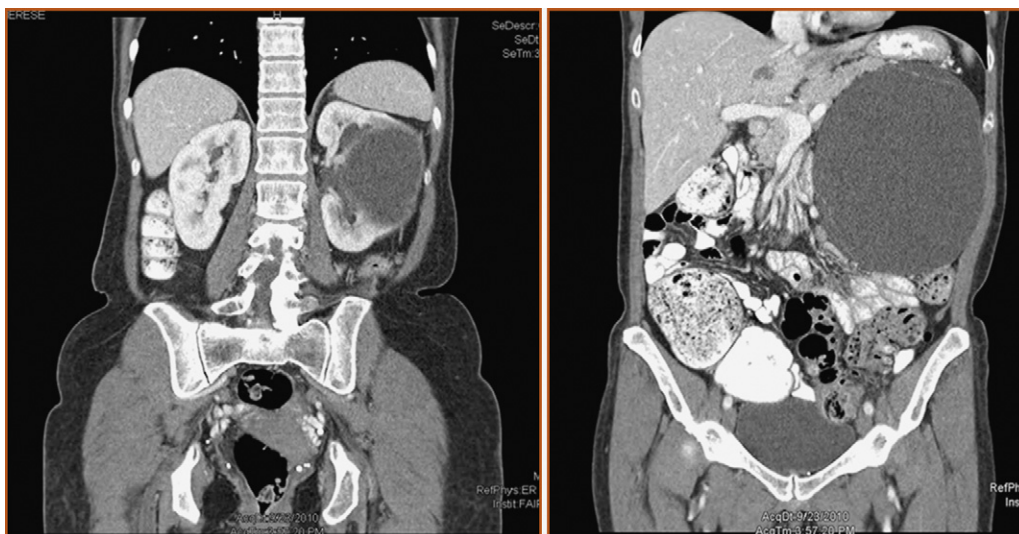


Fig. 5 – Computed tomography scan showing a Bosniak II left renal cyst measuring 12.4 × 13.1 × 15 cm.

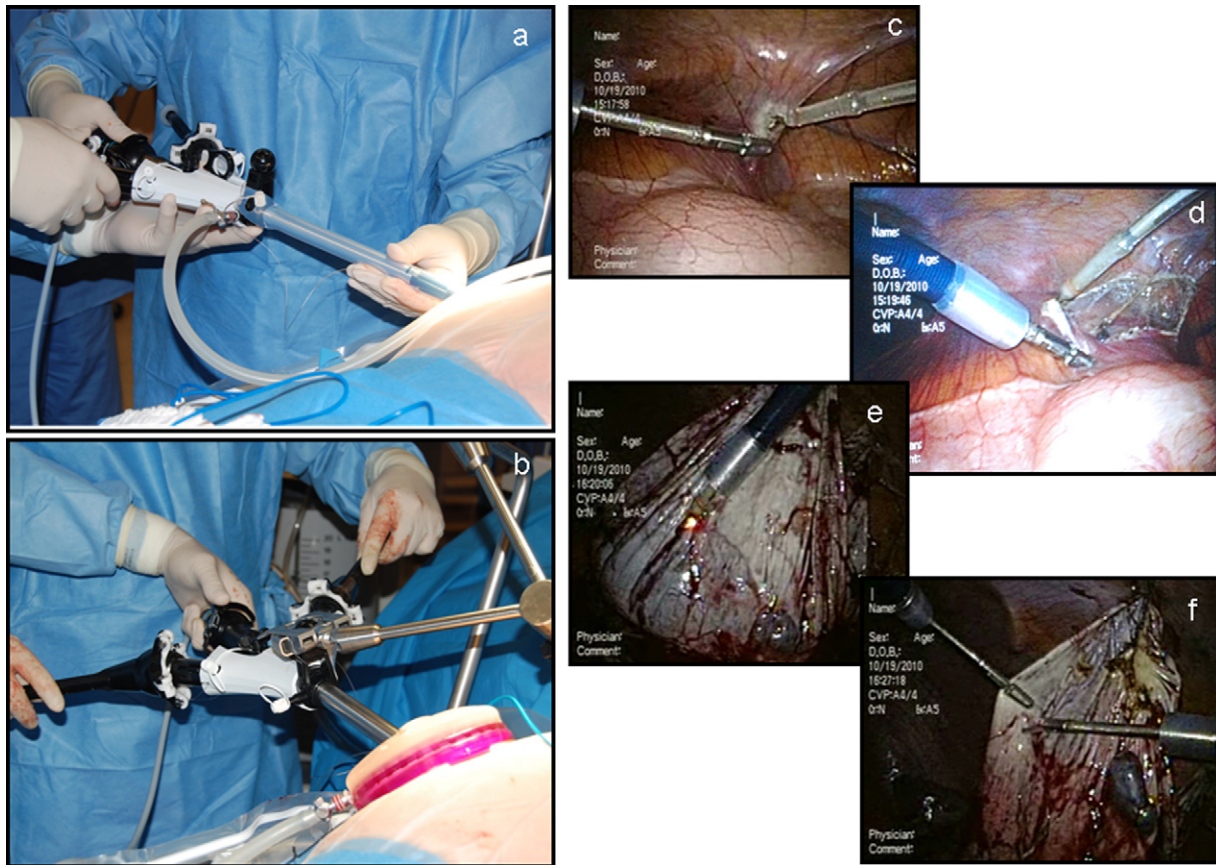


Fig. 6 – Cyst decortication: (a) SPIDER surgical system in position; (b) SPIDER surgical system through the GePOINT port; (c–f) intraoperative images.

the first clinical case ever reported in the literature. We also had the opportunity to assess a second-generation SPIDER system, which features articulating reduced-length IDTs and a vertebral design to increase the forces generated at the distal instrument tips.

The experience of the performing surgeons represents an important variable when testing a new surgical device. Laboratory evaluation showed that surgeons with different levels of expertise were able to gain an acceptable level of proficiency in performing different tasks. This kind of

assessment carries its own biases, but it provided us with an idea of how the surgeons perceived their level of comfort when handling this platform. The clinical case was performed by a surgeon with advanced laparoscopic skills and previous experience with LESS, but this fact did not prevent the surgeon from pointing out platform limitations.

Overall, the surgeons had a positive experience with the SPIDER system and provided the highest scores for ease of device insertion, ease of flexible instrument insertion/exchange, and triangulation. The lowest mean score was for

Table 1 – SPIDER surgical system laparoendoscopic single-site urologic surgery in the porcine model: perioperative outcomes

Procedure	Surgeon's level of expertise*	Side	OR time, min	Suturing time, min	EBL, ml	Complications	Addition of an extra port	Time to hilar control, min	WIT, min
Nephrectomy	Low	L	90	–	100	Bleeding	Yes (1 × 5 mm)	60	–
	Medium	R	75	–	0	No	No	35	–
	High	L	45	–	0	No	No	20	–
PN	High	R	67	24	0	No	No	19	29
	Medium	R	65	22	0	No	No	25	29
	Medium	R	90	21	80	Bleeding	No	60	28
Pyeloplasty	High	R	45	30	0	No	No	–	–
	Low	L	60	38	0	No	No	–	–
PC	Medium	–	85	20	0	No	No	–	–

OR = operating room; EBL = estimated blood loss; WIT = warm ischemia time; L = left side; R = right side; PN = partial nephrectomy; PC = partial cystectomy; LESS = laparoendoscopic single-site surgery.

* Low: early laparoscopic experience; medium: advanced laparoscopic experience and limited LESS experience; high: advanced LESS experience.

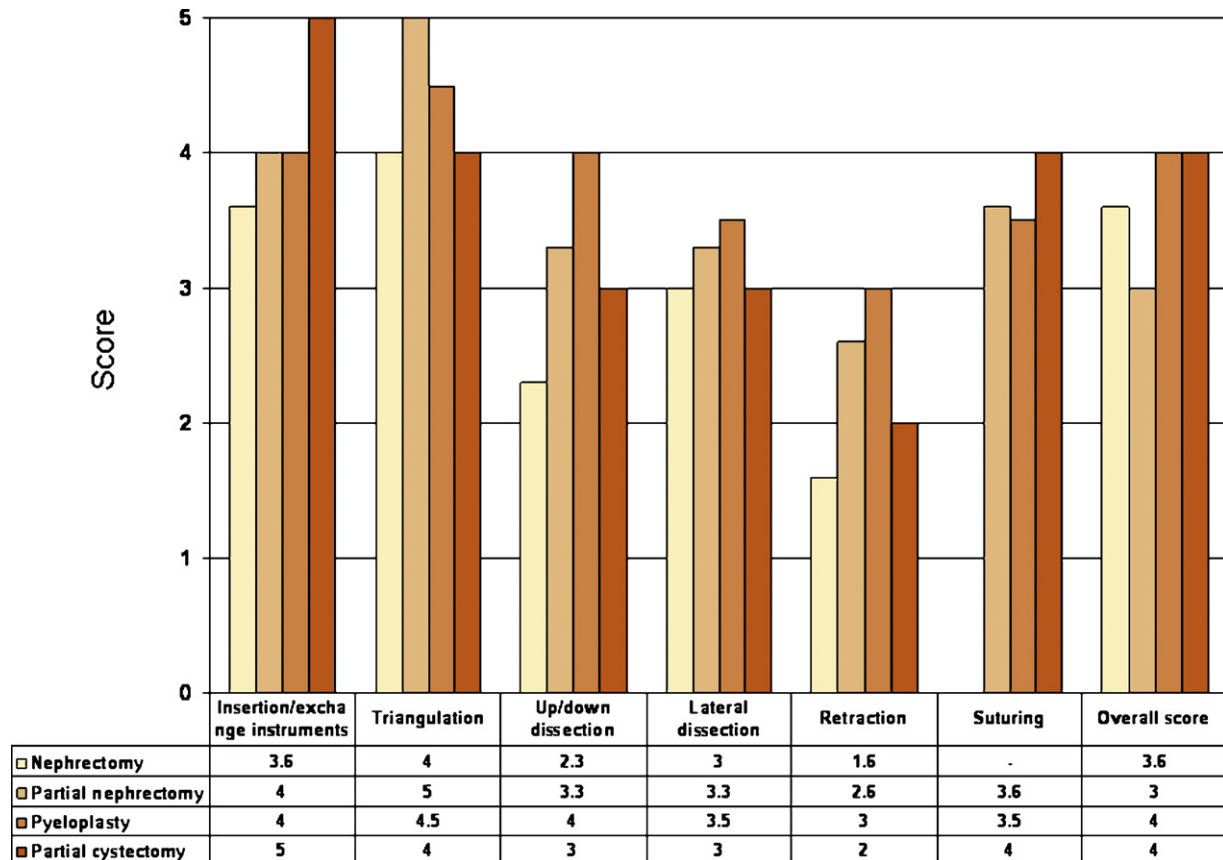


Fig. 7 – Evaluation for each subjective parameter based on a Likert-type scale (values expressed as means; score range: 1–5). Ease of device insertion scored 5 in all applicable cases. Ease of device fixation was considered intermediate (mean score: 3 ± 0.7). The mean score given to ease of insertion and exchange of the flexible instruments was 4 ± 1.1 . Triangulation had a mean score of 4.4 ± 0.5 . Up and down dissection was scored at 3.1 ± 0.8 , and lateral dissection had a mean score of 3.2 ± 0.7 . Retraction was scored at 2.3 ± 0.7 on average. Suturing had a mean score of 3.7 ± 0.5 . The mean overall score was 3.6 ± 0.5 .

instrument retraction. Among the perceived limitations, it is worth mentioning the lack of depth control while cutting, which is also related to the profile of the scissors, and the poor stability of instrument tips when completely exposed, which might hinder suturing capability.

Careful patient selection is recommended in the early phase of LESS skill acquisition to minimize complications and optimize surgical outcomes. Although more complex urologic procedures have proven feasible in the hands of experienced surgeons, renal cyst decortication can represent a reasonable initial indication for LESS in centers at the beginning of their experience. Early LESS series [3] as well as more recently reported cases [15] included examples of cyst decortication. During this first clinical case, the first-generation SPIDER platform and its flexible laparoscopic instruments provided good triangulation without clashing. The main problem with LESS procedures is instrument clashing and a lack of triangulation [3], which this device specifically addressed.

During the different surgical steps, the SPIDER system was repositioned as needed to allow optimal working angles. This movement might have accounted for a prolongation of the operative time, but the surgeons achieved device positioning and docking comfortably. Basic

maneuvers such as dissecting, retracting, grasping, cutting, and cauterizing were performed with difficulty because of a lack of strength and precise maneuverability when instrument tips were fully deployed. A surprising finding was the opening of the collecting system, which required suturing. Alongside the SPIDER system, straight laparoscopic instruments were inserted through the same incision and port where necessary. It can be speculated that the second-generation device would overcome the limitations our surgeons encountered.

Comparative studies are needed to ultimately evaluate any novel surgical platform. Even if this evaluation were not accomplished in the present study, we were able to show for the first time the feasibility of multiple urologic procedures in an animal model and to describe the first-ever reported clinical case.

The SPIDER surgical system represents a new concept in the field of the LESS armamentarium, offering intuitive maneuverability of instruments in the abdominal cavity, restored triangulation without external instrument clashing, and no significant gas leakage. Drawbacks of the first-generation system include its challenging clinical application, and further refinements are awaited to define the role of the system.

Conflicts of interest: The authors have nothing to disclose.

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EU-ACME questions

Please visit www.eu-acme.org/europeanurology to answer the following EU-ACME questions online (the EU-ACME credits will be attributed automatically).

Questions:

1. Among the features of laparoendoscopic single-site surgery (LESS) versus standard multiport laparoscopy is:
 - A. Need of a flexible scope
 - B. Lack of triangulation
 - C. Application for upper urinary tract procedures only
 - D. None of the above
2. The SPIDER platform is designed to allow:
 - A. Multiple surgical instruments to be manipulated through a single port
 - B. Introduction of robotic arms into the abdomen
 - C. Use of flexible instruments through instrument delivery tubes
 - D. A and C
3. Which of the following tasks is among those included in the Fundamentals of Laparoscopic Surgery program?
 - A. Peg transfer
 - B. Precision cutting
 - C. Suturing using intracorporeal knot tying
 - D. All of the above
4. Which of the following purpose-built platforms for laparoendoscopic single-site surgery have been described for clinical use in urology?
 - A. TriPort
 - B. SILS port
 - C. GelPOINT port
 - D. X-CONE port
 - E. All of the above

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