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Case Series of the Month

Robotic Urologic Surgical Interventions Performed with the Single Port Dedicated Platform: First Clinical Investigation

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Abstract

We report the first clinical investigation for surgical procedures performed using the da Vinci SP robotic surgical platform (Intuitive Surgical, Sunnyvale, CA, USA) during the first 10 days (September 28–October 12, 2018) after the system was installed at our institution. The aim of the study was to determine the feasibility and safety of major urologic procedures, measured as the rate of conversions and the incidence of perioperative complications. Secondary aims of the study consisted of key perioperative surgical outcomes, including operative time, blood loss, and length of stay. Pathology data were reported. Data collection was performed under institutional review board approval (IRB 13-780). A total of nine patients were treated (3 robot-assisted radical prostatectomies, 3 transperitoneal robot-assisted partial nephrectomies, 1 simple cystectomy with intracorporeal ileal conduit urinary diversion, 2 ureteral reimplantations). No intraoperative complications occurred. In six cases the surgeries were performed according to a pure single-site approach. The mean operative time was slightly longer than that reported for the corresponding multiarm robotic procedures in the literature, which can easily be explained by the expected learning curve. One minor and one major complication occurred. A learning curve exists when embarking with this surgery. Further investigations are awaited.

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1. Case series

Prospective data collection for this series was conducted by investigators from the Cleveland Clinic (Cleveland, OH, USA). The surgical procedures were performed by a single surgeon (J.K.) using the da Vinci SP robotic surgical platform (Intuitive Surgical, Sunnyvale, CA, USA) during the first 10 days (September 28–October 12, 2018) after the system was installed. Data for perioperative outcomes were collected under institutional review board approval (IRB 13-780). Subjects provided informed consent after adoption of the novel surgical platform had been explained to them. No specific inclusion or exclusion criteria were considered.

All the surgeries were completed via a 2.5–4-cm incision through which a GelPOINT standard (purple) or mini (green) advanced access platform (Applied Medical, Rancho Santa Margarita, CA, USA), and a dedicated 25-mm multichannel port accommodating an articulating robotic camera (12 mm × 10 mm), three 6-mm double-jointed articulating robotic instruments, and a 6-mm accessory laparoscopic instrument were placed. When needed, an additional port for the bedside assistant was placed either transabdominally or through the GelSeal cap, as previously described in our preclinical experience (Fig. 1) [1]. The robotic and laparoscopic instruments used during the procedures are reported in Supplementary Table 1.

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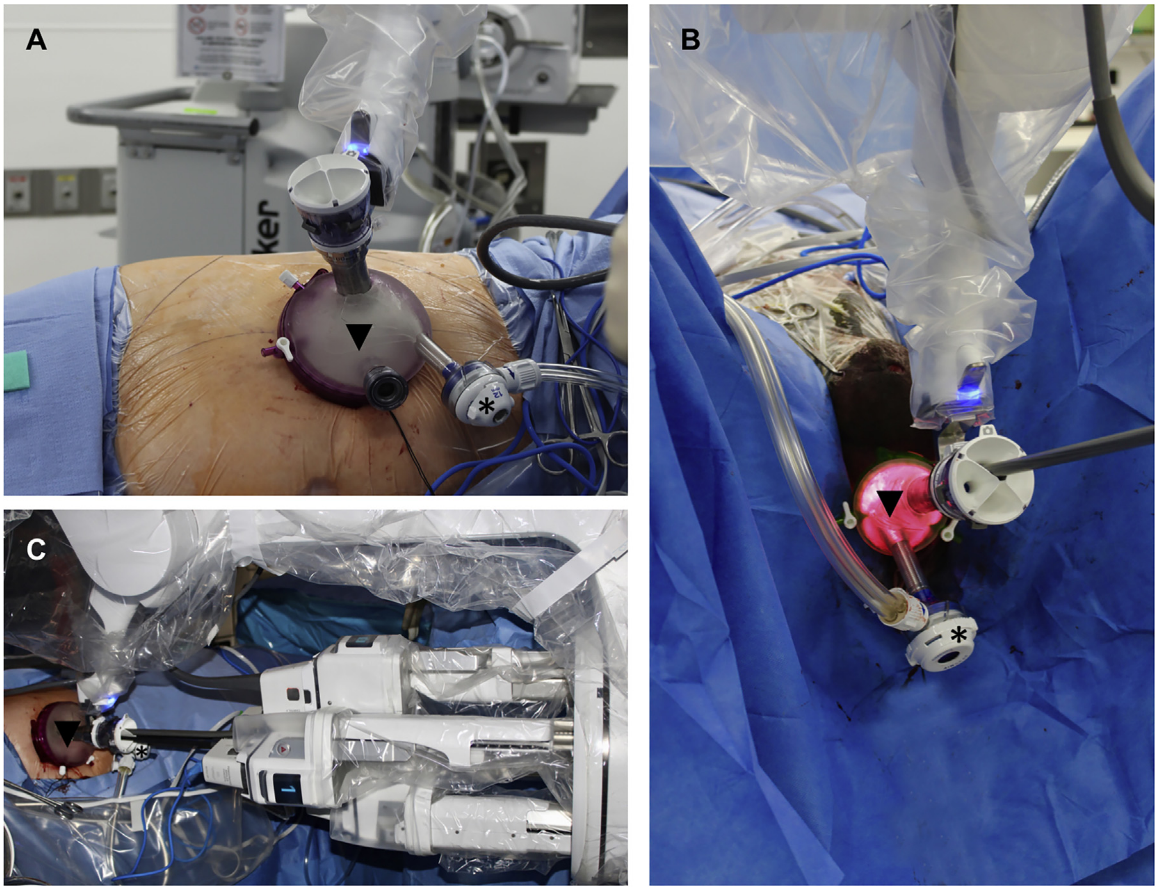

Fig. 1 – GelPOINT advanced access platforms (▼) (Applied Medical, Rancho Santa Margarita, CA, USA) accommodating the dedicated 25-mm multichannel port. (A,C) Standard GelPOINT platform (purple color) inserted through a 4-cm incision. (B) Mini-GelPOINT platform (green color) inserted through a 2.5-cm incision. A 10-mm port for the bedside assistant is placed through the GelSeal cap (*).

1.1. Outcome measurements

The aim of the study was to determine the feasibility of major urologic procedures, measured as the rate of conversions, and to evaluate the safety of the procedures, measured as the incidence of perioperative complications. A conversion was defined as an emergent change in the treatment plan to conventional laparoscopic/robotic surgery (ie, use of more than one additional port) or to open surgery. The Clavien system was used to grade the severity of postoperative adverse events [2]. Major complications were defined as Clavien grade ≥3. The secondary aims of the study consisted of assessment of key perioperative surgical outcomes, including operative time, blood loss, and length of hospital stay. Pathology data were reported.

2. Results

A total of nine patients were counseled for potential enrollment. All patients consented to undergo the surgery performed with the da Vinci SP surgical system. The demographic and clinical characteristics of the patients are reported in Table 1. Procedures performed included three robot-assisted radical prostatectomies (2 performed via a transperitoneal and 1 via a transperineal approach; Fig. 2), three transperitoneal robot-assisted partial nephrectomies (Fig. 3), one simple cystectomy with an intracorporeal ileal conduit urinary diversion, and two ureteral reimplantations (1 paired to bladder diverticulectomy and litholapaxy; Fig. 4). Perioperative outcomes for the surgeries are reported in Table 1. No intraoperative complications occurred and the mean operative time was 200 min. Intraoperative blood losses were negligible; one patient required angioembolization after partial nephrectomy. In six cases (including all the robot-assisted partial nephrectomies and the transperineal robotic prostatectomy) the surgeries were performed using a pure single-site approach (no additional ports were placed outside the GelPOINT platform).

3. Discussion

The recent advances in surgical robotics combined with the pursuit to reduce the invasiveness of laparoscopic surgery have led to the development of novel robotic platforms specifically designed for single-port surgery [3]. Among the

Table 1 – Demographic data, clinical characteristics, and perioperative and pathology data [a]

Age (yr)	Sex and race	Clinical scenario	Perioperative data	Postoperative data	Pathology	PODD
RA radical prostatectomy + pelvic lymph node dissection						
69	Male, White, non-Hispanic	PC GS 3 + 4 in 13/15 cores (3 on PIRADS 5 ECE+ lesion) PSA 3 ng/ml	OT 200 min EBL 50 ml	No complications	PC GS 3 + 4, pT3b pN0 (0/17) R+	POD 0
72	Male, White, non-Hispanic	PC GS 3 + 3 in 3/18 cores (3/3 on PIRADS 4 area) PSA 48 ng/ml	OT 180 min EBL 100 ml	No complications	PC GS 4 + 3, pT2 pN0 (0/13) R0	POD 1
47 [b]	Male, Black	PC GS 3 + 4 in 4/19 cores PSA 3.2 ng/ml	OT 300 min EBL 100 ml	No complications	PC GS 3 + 4, pT2 pNx R0	POD 1
RA partial nephrectomy						
63	Female, White, Hispanic	L renal mass, 1.5 cm, RENAL score 5 SCr 0.6 mg/dl	OT 150 min WIT 18 min EBL 300 ml 90% PP	SCr 0.9 mg/dl Hb 11.5 g/dl No complications	Papillary RCC pT1a R0, 1.6 cm ISUP 3	POD 3
68	Male, White, non-Hispanic	L renal mass, 2.4 cm, RENAL score 7 SCr 1.2 mg/dl	OT 210 min, WIT 28 min EBL 100 ml 85% PP	SCr 1.1 mg/dl Acute bleeding: Hb ↓ to 7.6 g/dl Transfusions + angioembolization (Clavien IIIa)	Chromophobe RCC pT1a R0, 1.7 cm ISUP not applicable	POD 4
70	Female, White, non-Hispanic	R renal mass, 2.9 cm, RENAL score 7 SCr 0.9 mg/dl	OT 200 min WIT 30 min EBL 150 ml 85% PP	SCr 1.01 mg/dl Hb 11.2 g/dl No complications	Clear cell RCC pT1a R0, 3 cm ISUP 3	POD 3
RA ureteral reimplantation						
54 [c]	Male, White, non-Hispanic	BPH, rUTI, large bladder diverticulum compressing the L ureter SCr 0.8 mg/dl	OT 150 min EBL 50 ml	SCr 0.79 mg/dl Nausea/vomiting after discharge (Clavien I)	Benign urothelial mucosa with squamous metaplasia	POD 1
45	F, Black	L ureteral stricture after hysterectomy SCr 1.2 mg/dl	OT 165 min EBL 30 ml	SCr 1.19 mg/dl No complications	Benign ureter with submucosal edema and inflammation	POD 1
RA simple cystectomy with intracorporeal ileal conduit urinary diversion						
70	Male, White, non-Hispanic	PC and EBRT with resultant radiation cystitis	OT 330 min EBL 100 ml	Hb 9.2 g/dl (11 g/dl preop.) No complications	Benign urothelial mucosa with ulceration	POD 4

RA = robot-assisted; PC = prostate cancer; GS = Gleason score; PZ = peripheral zone; ECE = extracapsular extension; PSA = prostate-specific antigen; OT = operative time; EBL = estimated blood loss; PODD = postoperative day discharge; TZ = transitional zone; SCr = serum creatinine; PP = parencyhmal preservation; WIT = warm ischemia time; Hb = hemoglobin; RCC = renal cell carcinoma; ISUP = International Society of Urological Pathology; BPH = benign prostatic hyperplasia; rUTI = recurrent urinary tract infection; PMH = past medical history; EBRT = external beam radiation therapy.

[a] Case numbers were assigned according to a chronological criterion.

[b] Performed via a transperineal approach. No indication to perform lymph node dissection.

[c] With bladder diverticulectomy and litholapaxy.

latest developments in the field, the da Vinci SP1098 system (Intuitive Surgical) is a robotic platform purpose-built for single-site, single-port surgery [4]. Kaouk et al. [5] described the first clinical application of its earlier SP999 version and successfully completed major urologic procedures. The compact profile of the working element of the platform is suitable for operating within narrow spaces, and the feasibility of "unconventional" approaches to various urologic interventions has been investigated in a preclinical setting [6], including extraperitoneal renal surgery [7], transperineal and transvesical prostate surgery [8,9], and transperineal bladder surgery [10]. The latest da Vinci SP surgical system to be released received US Food and Drug Administration approval on May 31, 2018. Here we report the first case series of major urologic surgeries performed in living humans using the SP platform.

The da Vinci SP system includes three multijointed wristed instruments and a fully wristed three-dimensional high-definition camera. The instruments and the camera all emerge through a single multichannel port. The SP instruments incorporate an additional joint, providing an "elbow" so that instruments can be triangulated around the target anatomy. This feature represents the main advance with respect to existing systems not dedicated to a single port, and reduces the external instrument clashes that can occur in narrow surgical workspaces. Another important feature of the system is the 360° of anatomic access allowed by the single arm (Fig. 5). One noteworthy point is that our case series reported here includes the first robot-assisted radical prostatectomy performed via a transperineal approach using a purpose-built single-port platform.

Regarding outcomes for the procedures performed, there were no conversions, which demonstrates the feasibility of the new da Vinci SP surgical system for these indications. The mean operative time was comparable to that during the initial experience with the prototype surgical platform

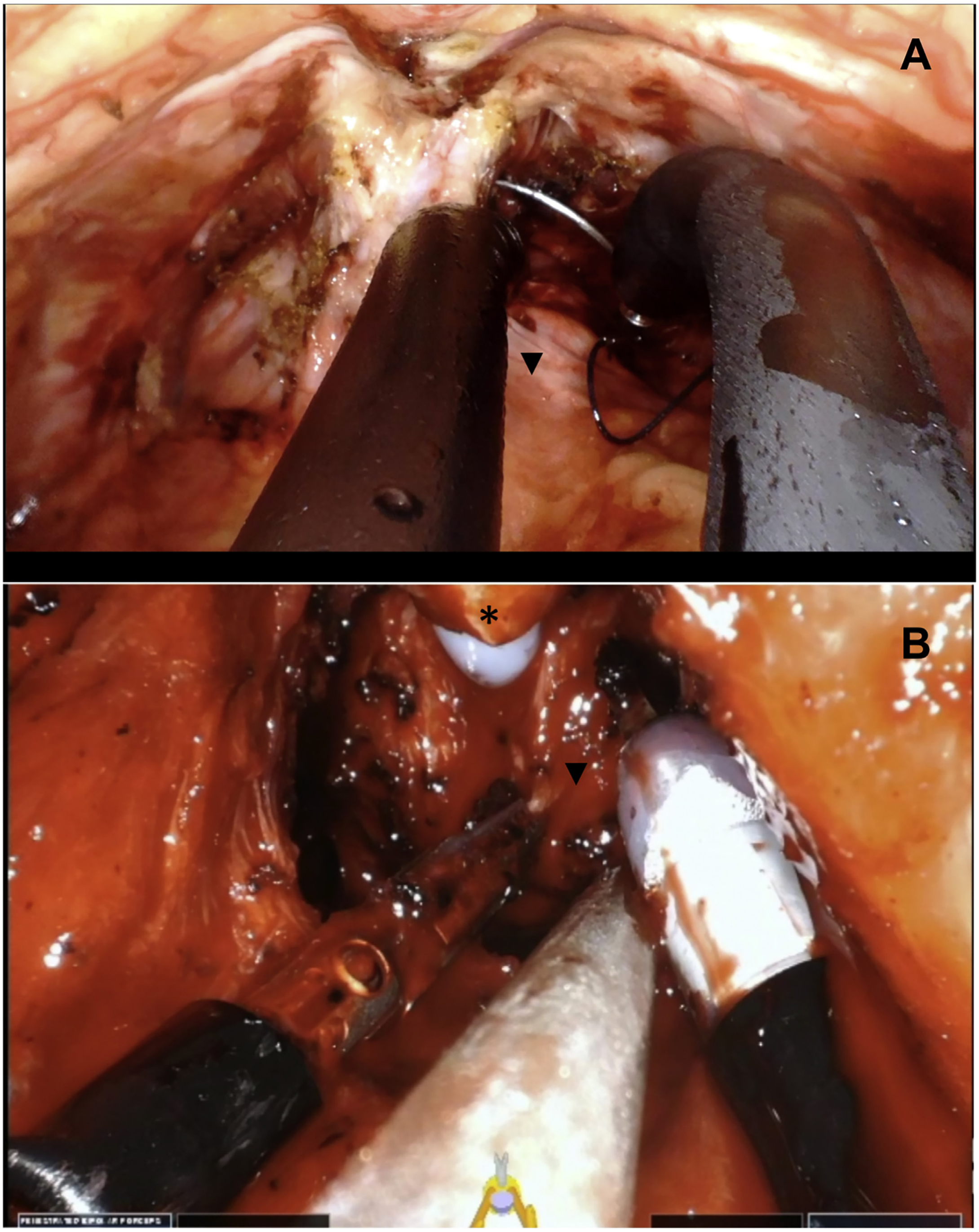

Fig. 2 – Steps for robot-assisted radical prostatectomy. (A) Deep venous complex ligation during a standard transperitoneal approach. (B) Apical dissection during a transperineal approach. The view of the anatomy is reversed (* = urethra, ▼ = prostate).

[5]. However, it was slightly longer than the mean times reported for the corresponding multiarm robotic procedures in the literature, which can easily be explained by the expected learning curve. Only one patient had a minor complication (nausea and vomiting after discharge, Clavien I). One patient underwent angioembolization for acute bleeding after partial nephrectomy (Clavien IIIa).

In the present study, six out of nine procedures were performed using a pure single-site approach and the cosmetic results were encouraging (Fig. 6). An extra port via a separate skin incision for the bedside assistant was placed only for the transperitoneal radical prostatectomies and the cystectomy. In these cases, the additional port was used electively from the start of the procedure and did not represent a change in the treatment plan. This was done to allow the bed-side assistant for enjoying more room during the procedure. Challenges related to bedside assistance represent a major issue during laparoendoscopic single-site

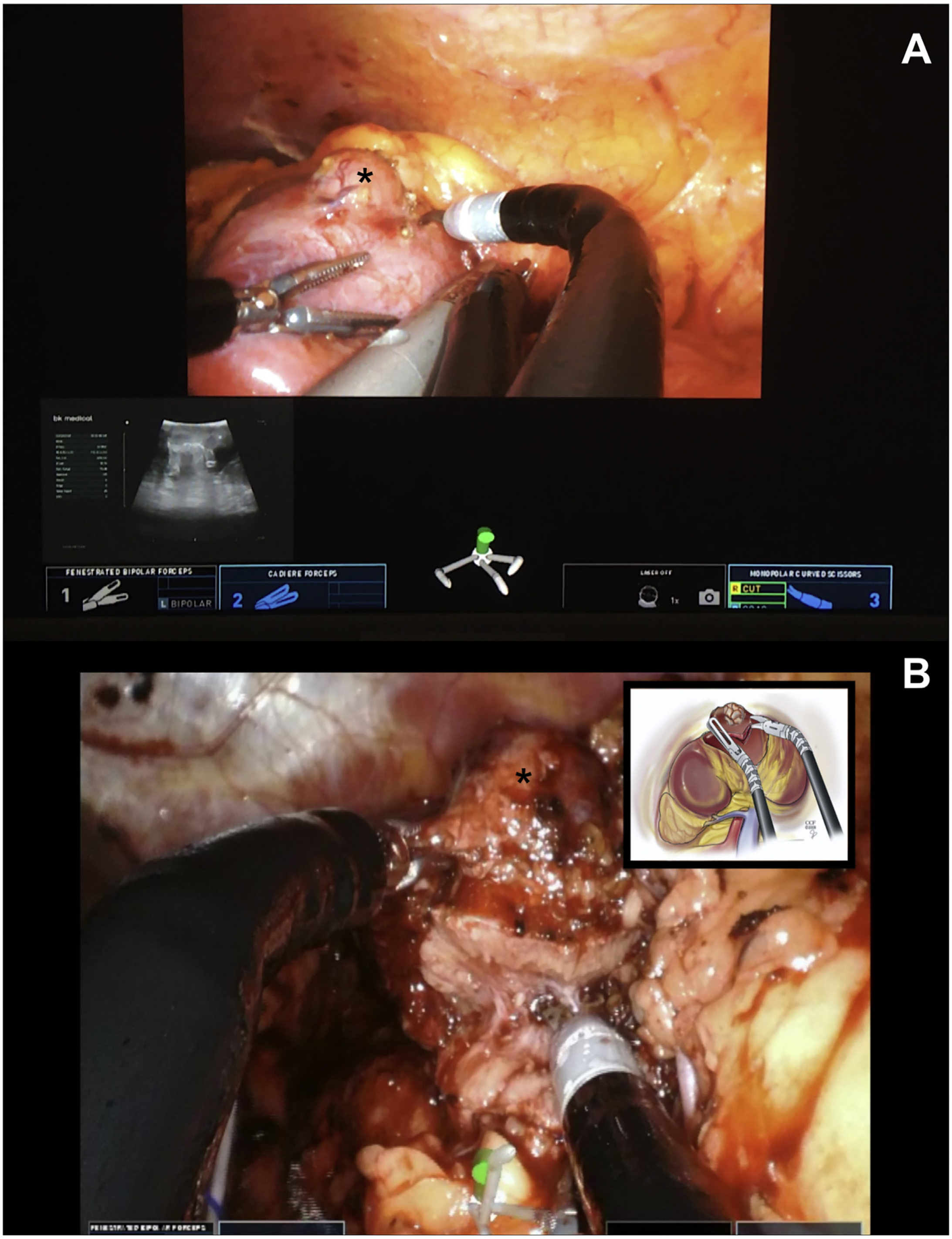

Fig. 3 – Tumor (*) resection during robot-assisted partial nephrectomy. (A) Intraoperative ultrasonography (Tile-Pro view) with the tumor boundaries marked. (B) Resection phase (in vivo and in sketch). The cartoon shows the position of the instruments in real time (optics in green).

surgery, as previously reported [3]. We acknowledge that this issue is not completely solved with the SP robotic system because access to the surgical field for the assistant remains challenging. Good coordination between the console surgeon and the assistant is also required owing to the limited working space when using the SP platform. Moreover, since the camera and instruments are all inserted through a single port, the surgeon often needs to adjust the camera or move the whole camera-instruments block to retarget the anatomy of interest, particularly when navigating larger anatomic spaces.

We underline that a learning curve exists when embarking on this surgery. After the early experience reported here, we are unable to suggest a minimum number of procedures to perform before surgeons can feel confident with the technology. Ideally, we suggest consistent robotic

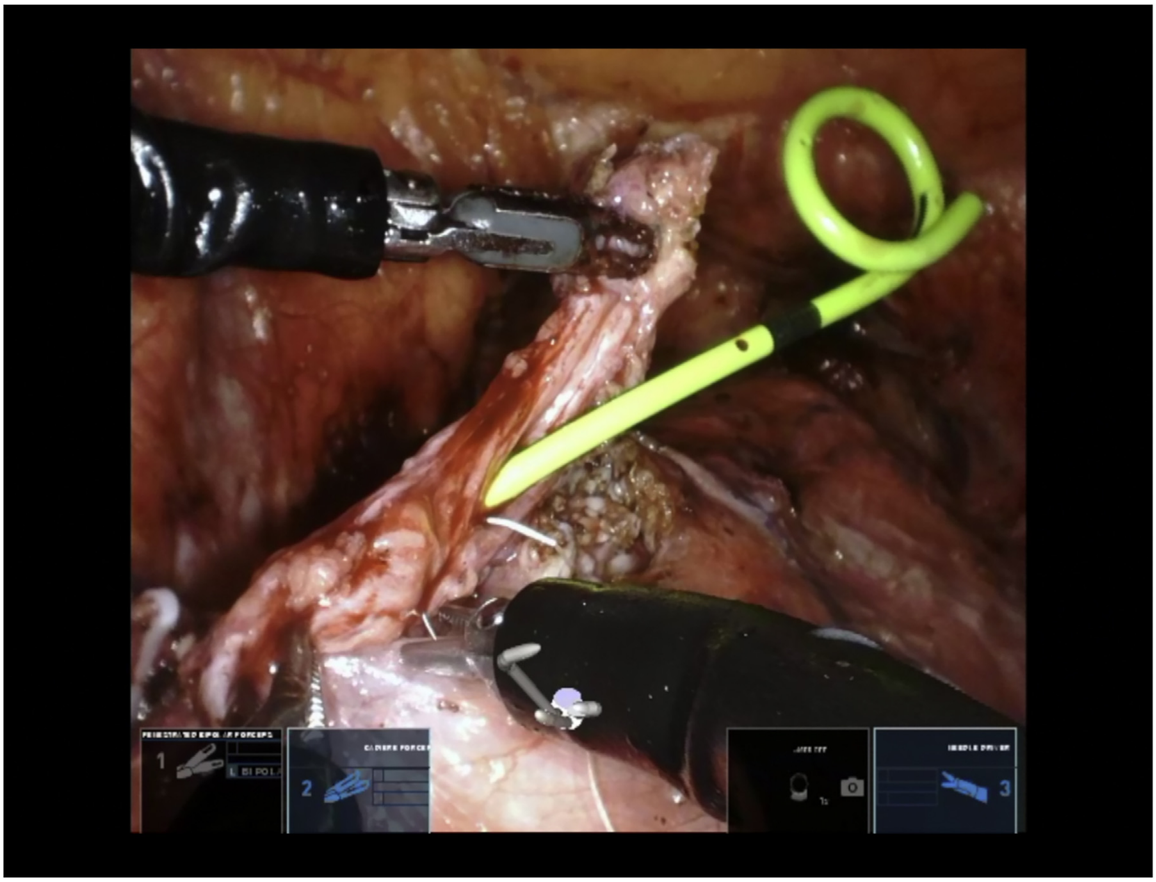

Fig. 4 – Surgical step for ureteral reimplantation.

Fig. 5 – Typical intraoperative room set-up during transperineal robot-assisted prostatectomy.

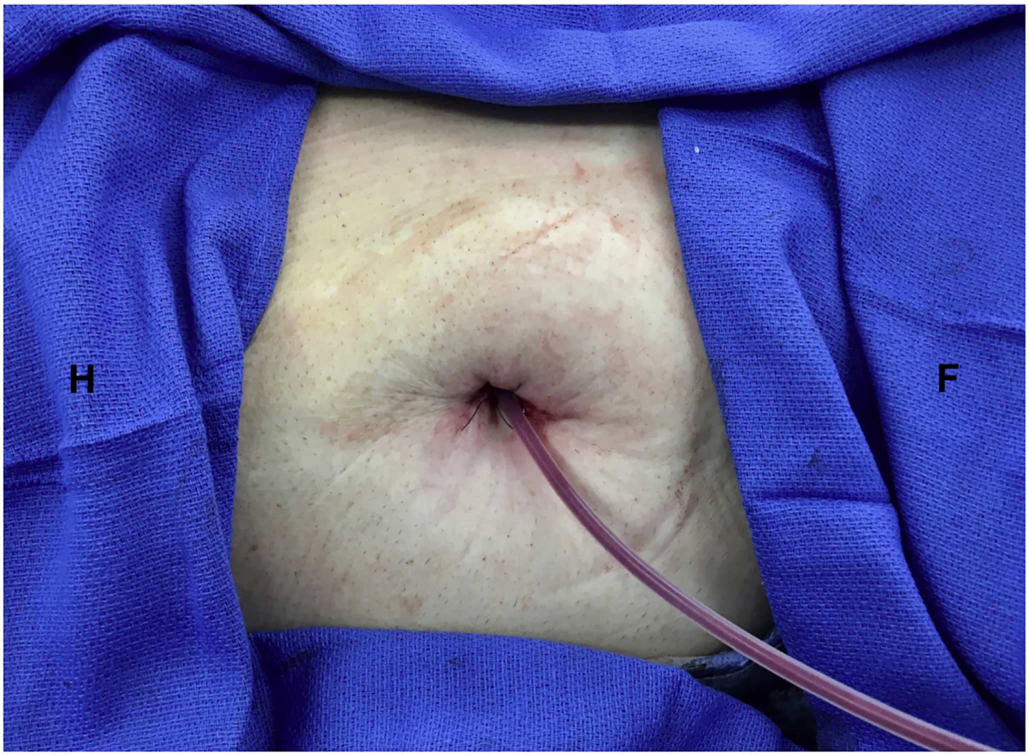

Fig. 6 – Final result after robot-assisted partial nephrectomy (H = head, F = feet).

experience. The instruments of the SP surgical system allow degrees of freedom comparable to those of the standard multiport da Vinci platforms, but differences can be perceived, particularly during intracorporeal suturing, because of the novel elbow, so the dynamic for suturing is modified. We believe that loss of the EndoWrist technology could mostly affect expert robotic surgeons (with a consistent number of procedures performed using the earlier multiarm da Vinci platforms).

Comparative studies for standard laparoendoscopic single-site surgery and multiport robotics are needed. Moreover, larger sample sizes and longer follow-up are awaited. The urology community needs to define the optimal indications for the novel platform to investigate in future clinical studies. We hypothesize that multiarm robots will probably remain the standard for transperitoneal prostatectomy. Partial nephrectomy could be redefined by the advent of the new platform because of the potential to use a single access point for the treatment of both posterior and anterior renal masses. Minimization of the invasiveness for cystectomy with intracorporeal urinary diversion is attractive. We feel that ureteral reconstructive surgery is one of the most promising indications. Moreover, the potential for avoiding the abdominal cavity for surgeries of the pelvic fossa via a transperineal (or transvesical) approach and the perspective of single-docking universal access for multiquadrant surgery such as kidney autotransplant or bilateral ureteral strictures repair are likely to be in the future of the SP surgical system.

Conflicts of interest: Jihad Kaouk is a consultant for Endocare and Intuitive Surgical. The remaining authors have nothing to disclose.

EU-ACME question

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Question:

What is the correct chronological sequence in which the da Vinci single-port purpose-built surgical platforms have been tested?

A. SP1098 → SP999 → SP
B. SP999 → SP1098 → SP
C. SP → SP999 → SP1098
D. SP → SP1098 → SP999
D. SP → SP1098 → SP999

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.eururo.2018.11.044.

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