Robotic One Access Surgery (R-1): Initial Preclinical Experience for Urological Surgeries

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Laparoendoscopic single-site surgery was developed to minimize the morbidity associated with laparoscopic surgery. Application of robotics in urologic surgery has been widely adopted given the advantages it provides over standard laparoscopy including 3-dimensional vision, improved ergonomics, enhanced precision and dexterity. The real benefit of robotic laparoendoscopic single-site surgery is still unbalanced by the limitations of this approach and the sole applicability by highly skilled surgeons. The ideal robotic platform for single-port surgery should have the possibility of being deployed through a single access site restoring intracorporeal triangulation for precise instrument maneuvers. This manuscript reviews the potential applications of R-1 new surgical robot, highlighting its added value in allowing new surgical approaches. UROLOGY 133: 5–9, 2019. © 2019 Elsevier Inc.

In the past 15 years, robotic surgical platforms have become a commonly utilized tool for minimally invasive surgical procedures in urology. The available platforms utilize multiple points of entry in order to achieve separation of the instruments (ie, "triangulation") and interplay between console surgeon and bedside assistant. Attempts have been made to achieve surgical access through single ports of entry via laparoscopic or robotic technique. However, available surgical robots do not specifically conform to single-port surgeries, with instrument collision being a major challenge. The ideal robotic platform for single-port surgery should have a low external profile, the possibility of being deployed through a single access site and the capability of restoring intracorporeal triangulation, while maintaining a reasonable degree of freedom for precise maneuvers and strength for reliable traction. The ideal single-port platform would combine multiple features and increase the feasibility and adoption of robotic laparoendoscopic single-site surgery (LESS).

In view of recent approval by the FDA of the Intuitive Surgical's first "purpose designed" single-port robot platform, we present a review paper with the current state of knowledge from a working group of robotic surgery experts. The content of the paper includes both key literature review, and a description from a preclinical laboratory experience using the da Vinci SP1098 (Intuitive Surgical, Sunnyvale, CA). This is the premarketing release version of the device. Topics on this review includes: (1) design of the single-port robotic platform and previous clinical experience, (2) current laboratory evaluation, (3) training and learning curve, and (4) potential credentialing challenges. To improve search ability of related literature, the authors have designated the term R-One (R for robot and One for 1 surgical access site) as a reference name for this device and its surgical applications.

DESIGN AND PREVIOUS CLINICAL EXPERIENCE

While the da Vinci robotic system has substantially improved our ability to perform robotic laparoendoscopic single site (R-LESS) surgery, it was not originally designed for this purpose (Fig. 1), which led to the development of the da Vinci single-port, SP999—now R-One. In contrast to the original robotic design, that requires the use of multiple separate ports, R-One only uses a single port to introduce the instruments and camera. The base of the surgical cart is similar to the Xi's, but only has a single arm. The surgical console and video tower are Xi models and with

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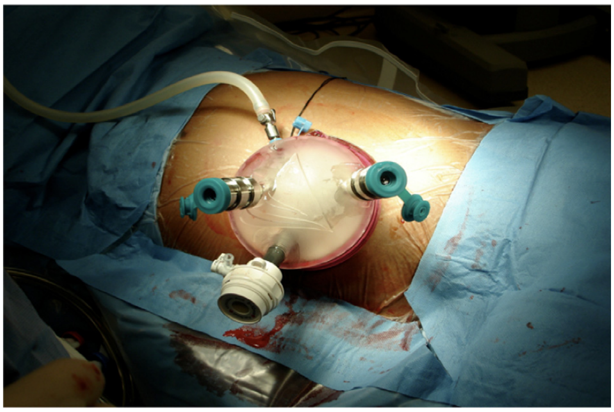

Figure 1. Robotic Laparoendoscopic Single Site Surgery (R-LESS). Note that the 12-mm camera holder port and 2 additional robotic ports are all inserted in the periumbilical area through a GelPoint (Applied Medical, Rancho Santa Margarita, CA). (Color version available online.)

future software upgrades will be plug-and-play compatible with a multiarm Xi patient cart. Robotic cart can be placed from any angle around the patient (Fig. 2).

The designs of the articulating endoscopic camera and 3 double-jointed articulating endoscopic instruments (Supplement Fig. 1), which enter the patient through a multichannel robotic port (25 mm cannula). Four robotic manipulators, or instrument drives, that control the camera and instruments are mounted on an instrument arm that is attached to the patient side cart. Unique to this robotic system is the ability to clutch and pivot the instrument arm about its remote center without moving each individual instrument.[1]

In 2014, Kaouk et al[2] was the first to clinically assess the feasibility and safety of urologic procedures using the new generation robot (SP 999, intuitive surgical, Sunnyvale, CA). After obtaining IRB approval, 8 patients underwent preoperatively planned nephrectomy procedures that consisted of 4 partial nephrectomies, 2 radical nephrectomies, 2 simple nephrectomies, and 11 subjects submitted to radical prostatectomy. The authors concluded that major urologic procedures were successfully completed without conversions, or major complications.

Since then, further enhancements of the robot optics and controls were performed (SP 1098, intuitive surgical, Sunnyvale, CA). In 2017, Maurice et al[3] assessed R-One retroperitoneal renal surgery feasibility in a preclinical study (Supplement Fig. 2). Tables 1 and Supplement Table 1 summarize key literature findings in RLESS procedures and form the foundation for early clinical and laboratory testing the new R-ONE platform.

CURRENT PRECLINICAL LABORATORY EXPERIENCE

Over the course of a 2-day/16 hour cadaver laboratory, a group of urologists with expertise in robotics and prior single-port platforms worked through a comprehensive agenda to evaluate several aspects of this novel technology.

Different urological procedures were performed including transperineal, transvesical, transperitoneal access to

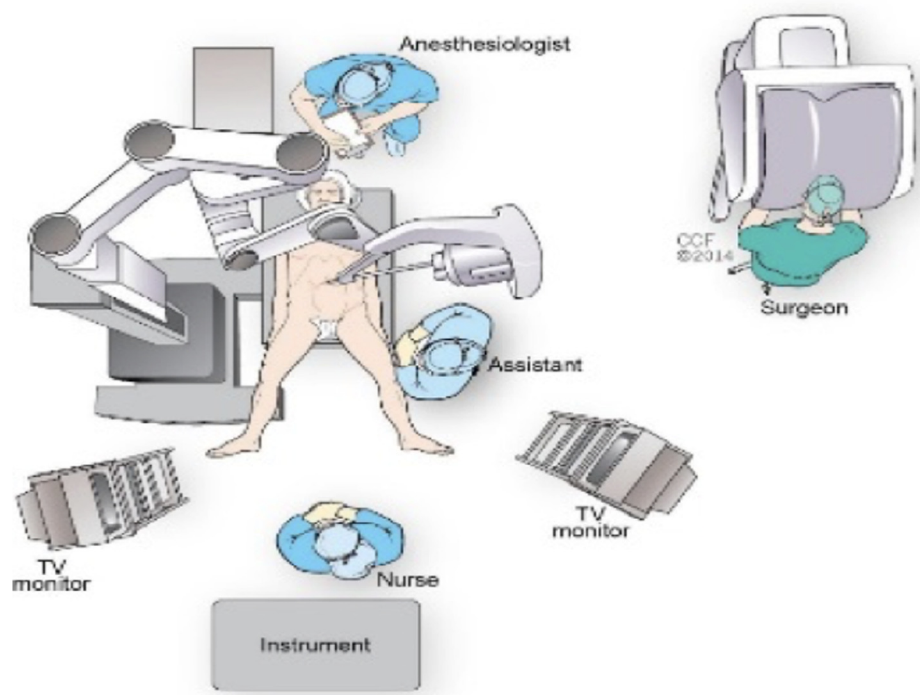

Figure 2. Operating room theater setup for R-One surgery. The robotic cart can be placed from any angle around the patient. The single access approach allows for multiquadrant surgery through he same incision. (Color version available online.)

Table 1. Evolution of R-LESS technology and summary of initial clinical studies

Study	Technique	Year	Center	Surgery	Approach
Kaouk el al[4]	R-LESS using Si Robot	2008	CCF	Radical prostatectomy ($n = 1$), dismembered pyeloplasty ($n = 1$), radical nephrectomy ($n = 1$)	TU-TP
Stein et al[5]	R-LESS	2010	CCF	Pyeloplasty ($n = 2$), radical nephrectomy ($n = 1$) partial nephrectomy ($n = 1$)	TU-TP
White et al[6]	R-LESS	2010	CCF	Radical Prostatectomy (n=20)	TU-TP
White al al[7]	R-LESS	2011	CCF	Radical Nephrectomy ($n = 10$) matched to laparoscopic approach	TU-TP
Arkoncel et al[8]	R-LESS	2011	Yonsei University College of Medicine	Partial nephrectomy (n=35) matched to conventional robotic approach	TU-TP
Lee et al[9]	R-LESS	2011	Yonsei University College of Medicine	Partial nephrectomy (n = 51), nephroureterectomy ($n = 12$), nephrectomy ($n = 3$), adrenalectomy ($n = 2$).	PU
Olweny et al[10]	R-LESS	2012	University of Texas Southwestern Medical Center	Pyeloplasty, comparing RLESS ($n = 10$) to conventional LESS ($n = 10$)	TU-TP
Fareed et al[11]	R-LESS	2012	CCF	Transvesical enucleation of the prostate ($n = 9$)	TV-extraperitoneal
Cestari et al[12]	R-LESS	2012	San Raffaele-Turro Hospital, Milan, Italy	Pyeloplasty ($n = 9$)	TU-TP
Seideman et al[13]	R-LESS	2012	University of Texas Southwestern Medical Center	Pyeloplasty ($n = 12$)	TU-TP
Khanna et al[14]	R-LESS	2012	CCF	Radical nephrectomies ($n = 11$), partial nephrectomies ($n = 5$), nephroureterectomies ($n = 3$), pyeloplasties ($n = 7$), simple nephrectomy ($n = 1$), renal cyst decortication ($n = 1$)	TU-TP
Tobis et al[15]	R-LESS	2013	University of Rochester Medical Center, NY	Pyeloplasty	TU-TP
Park et al[16]	R-LESS	2013	Yonsei University College of Medicine	Adrenalectomy ($n = 5$)	Retroperitoneal
Kaouk et al[2]	R-One Using SP robot	2014	CCF	Partial nephrectomy radical nephrectomy radical Prostatectomy	TU-TP
Kaouk et al[17]	R-LESS	2016	CCF	Perineal prostatectomy	Perineal

CCF, Cleveland Clinic Foundation; PU, periumbilical; R-LESS, robotic laparoendoscopic single site surgery; TP, transperitoneal; TU, transumbilical; TV, transvesical.

the pelvic fossa, and the transperitoneal and retroperitoneal access to the retroperitoneal space.

Surgical Procedures in the Pelvic Fossa

Transperitoneal Approach. Radical prostatectomy was the original procedure to launch the modern era of robotics in urology with most surgeons using the transperitoneal 4-arm/2 assistant-port technique. One practical consideration was to adapt R-One to an extraperitoneal transabdominal space, as has been reported in clinical experience.[23] To perform the R-One transperitoneal radical prostatectomy, a cadaver was placed supine in a 15° Trendelenburg position. A transumbilical incision was made to allow the insertion of the 2.5-cm robotic port. An extra 5-mm port was electively placed (right pararectal line below the umbilicus) and the preperitoneal space was established. The procedure replicated the same steps as the transperitoneal radical prostatectomy, which has been previously described.

Retzius-Sparing Approach

A transperitoneal retzius space sparing radical prostatectomy was performed. Similar to the transperitoneal approach, a periumbilical incision was made allowing the insertion of robotic port. Due to the initial experience, an additional 5-mm port was electively placed for the placement of clips. The prostate was approached from below the bladder, rather than above. The space developed by the surgeon operating with the R-1 is narrow with the position of the prostate and the bladder reversed, making the anatomy at first sight looks confusing. The urethrovesical anastomosis is also contrast from the conventional prostatectomy. In that term, the front aspect of the anastomosis has to be completed before the back wall, which is the reverse of the conventional procedure. The maneuverability of the R-1 instruments permits the completion removal of the prostate and reconstruction of the lower urinary tract via Retzius sparing.

Another approach with deep roots in the history of urology is the perineal.[24-25] Open perineal radical prostatectomy was described in 1905 and remained the most common approach for surgical treatment of prostate cancer until the mid 70s.[24] Laydner et al first investigated the applicability of the multiarm robotic surgical system for the perineal approach for radical prostatectomy.[26] During the procedure, drawbacks regarding the instruments clashing made the approach technically challenge. The R-1 can manipulate independently robotic instruments facilitating the tissue removal due to the natural intracorporeal triangulation.

For this approach, we placed our model in dorsal lithotomy position with a 15° Trendelenburg position facilitating access to the perineum. Then a 2.5-cm semilunar incision is made in the midline, between ischial tuberosities. The subcutaneous tissue is dissected and the central tendon of the perineal body is identified and cut. The rectourethralis muscle is transected to expose the space inferior to the membranous urethra. In this manner, the external sphincter is identified and retracted superiorly. At this point, the 2.5-cm specialized multichannel single-port trocar is placed and mounted with the access mini advanced access platform to allow a second access point for an assistant. The robotic device is then docked and standard insufflation pressures of 12-15 mm Hg (Supplement Fig. 3A).

Muscle fibers are split along the lateral aspects of the prostate, and Denonvilliers' fascia is opened (Supplement Fig. 3B). The posterior plane of the prostate is delineated and followed to find the insertion of the seminal vesicles and vas deferens bilaterally. This is followed by identification and ligation of bilateral vascular pedicles of the prostate. Sequentially, the junction between the bladder neck and prostate is identified and opened. Lastly, the anastomosis was performed in a running fashion beginning anteriorly and completed on the posterior aspect of the urethra. A standard critique of the open perineal prostatectomy was limited access to perform a lymph node dissection. R-One allows access, but will have the learning curve of encountering the anatomy from a significantly different angle. The single-port access port allows easy access to the obturator and external iliac nodal chains on either side, while maintaining exposure and triangulation of the robotic instruments. Overall, R-One in a male perineum can navigate approximately to the level of the common iliac artery before encountering bone collisions.[20]

Feasibility of perineal radical cystectomy, pelvic lymph node dissection (Supplement Fig. 4) and construction of ileal conduit urinary diversion was also described in a quest to explore boundaries and capabilities of employing the R-One through the transperineal approach.[20-21]

Finally, we attempted access via transvesical space. Standard robotic approaches are increasingly reported for simple prostatectomy, but radical planes are equally feasible (however lymph nodes are not). An incision was made halfway between the umbilicus and pubic symphysis to allow the insertion of the 2.5-cm robotic port directly into the bladder. A posterior bladder neck incision was deepened through the full thickness of the detrusor to expose the vasa and seminal vesicles. The vasa were divided bilaterally and both seminal vesicles were mobilized completely. Denonvilliers' fascia was incised and posterior dissection performed along the prerectal fat up to the prostatic apex. The posterior bladder neck incision was extended on both sides to encircle the bladder neck. The lateral prostate pedicles were divided using robotic scissors and the neurovascular bundles were released from the prostate capsule. The dorsal vein was ligated, with subsequent division of the urethra distal to the apex of the prostate. The vesicourethral anastomosis was made in a continuous fashion using 4-0 polyglactin sutures—Supplement Figure 5.

R-One Access Retroperitoneal Radical and Partial Nephrectomy

Upper Urinary Tract Surgery. The retroperitoneal approach has emerged as an alternative to transabdominal robotic adrenal and kidney surgery for posterior tumors. With the SP system, by using 1 single port, approaching posterior and anterior tumors is feasible using a retroperitoneal access. Both methods were demonstrated.

For a *transperitoneal* approach, the patient is positioned in a modified flank position at approximately 60°. A transumbilical incision or pararectal incision is made to allow the insertion of the 2.5-cm robotic port. One 12-mm assistant port is placed through the same skin incision alongside the single robotic port. The procedure is performed according to a previously described robotic partial nephrectomy steps.[27] Hilar occlusion is obtained and tumor resection performed. Renorrhaphy is accomplished using a "sliding-clip" technique. For exploratory applications, R-One was applied to Natural Orifice Transluminal Endoscopic Surgery as a transvaginal approach, and the instruments could be safely driven from a lithotomy position/vaginal access to the upper pole of the kidney and simulate a tumor excision and tumor bed repair (Supplement Table 2). Transrectal access was found to be feasible, although evaluation limited by the inability to bowel prep a cadaver. For the application to upper tract transitional cell carcinoma, R-One showed promise as a multiquadrant platform similar to Xi. The single arm can be repositioned in a wide range of approaches, that is, upper quadrant for nephrectomy to lower quadrant for distal ureterectomy/cuff excision. The instrumentation is similar to Xi, including the necessary needle drivers for intracorporeal suturing of the cystotomy.

For a *retroperitoneal* approach, the patient is placed in the full flank position and the table fully flexed to increase the space between the 12th rib and iliac crest. The port is placed at any point between the anterior axillary line and the paraspinous muscle (according to the location of the tumor, anterior or posterior), 2 cm above and medial to the iliac crest. The dissection and exposure is also the same for standard robotic partial nephrectomy.

RECONSTRUCTIVE PROCEDURES

As described in the radical prostatectomy section, there is potential for using the CO_2 insufflated bladder for surgical access. Radical prostatectomy was performed and by inference, simple prostatectomy would be feasible. Such procedures would eliminate contact with the peritoneal cavity and would be considered Retzius sparing. With a hybrid approach intra and extravesical, we demonstrated a reimplantation of the ureter—Supplement Figure 6.

Based upon the prostatectomy and ureteral reimplantation procedures, we concluded that the device has sufficient surgical access and instrumentation to expand case complexity to additional pelvic procedures such as Boari flap, vesical vaginal fistula, and sacrocolpopexy.

TRAINING AND LEARNING CURVE

R-One is an advanced robotic platform that will have significant learning curves for technical skill and case selection. It is assumed that surgeons pursuing this technology will be experts at standard multiport robotic procedures. Furthermore, it is assumed that R-One will excel at providing surgical access to smaller spaces that would be difficult to accomplish via multiport. The opposite may be true in that single-port access in a large space may not provide much patient benefit and may be constraining to the surgeon compared to multiport.

The specific learning curve technical tasks for R-One are mostly related to positioning the instruments: (1) docking this type of robot,[31] (2) learning to clutch and manipulate both the instrument platform as a whole as well as specific instruments (ie, 2 clutch mechanisms), (3) driving the camera, and (4) using the software icon and the clutching mechanisms to avoid both collisions and running out of instrument reach. Once these tasks are accomplished, there will be a learning curve for applying the instruments to a specific procedure and interplay with an assistant surgeon, who will likely have restricted access compared to multiport. On the other hand, once access is obtained, the actual tissue manipulation and suturing will be very familiar and smooth to the experienced multiport surgeon.

After our preclinical experience on the laboratory, the group of expert robotic surgeons feel that (1) 1-2 days of laboratory training will be required for learning docking and R-One specific setup and execution skills, (2) cadaver procedure practice will be required to gain efficiency in moving the instrument around larger spaces, and (3) additional training might be required to learn new surgical access points if not previously utilized. Further task evaluation with proctors and surgeons should be performed to assess these conclusions.

Credentialing

Initial credentialing for R-One will be difficult due to the novelty of the platform and a lack of available proctors. However, a safe pathway forward should be feasible with "layers" of credentials possible. As suggested, credentialed R-One surgeons should be expert multiport robotic surgeons who have completed 2 or more days of cadaveric-based training per above. The next tasks in safe operations will be case selection. As noted in our array of cadaver cases, there are relatively straightforward applications possible. Certainly a surgeon could first demonstrate proficiency in routine applications such as transperitoneal radical prostatectomy or partial nephrectomy, with a low threshold for placing additional assistant ports or even converting to multiport. The next phase can be applications into medium spaces such as extraperitoneal prostatectomy or retroperitoneal partial nephrectomy. The final phase would be novel spaces, such as, perineal prostatectomy or transvaginal nephrectomy or transvesical simple prostatectomy. As with any newer surgical technique, patient counseling with detailed documentation and informed consent will be critical, as well as transparency with individual experience and plans for conversion of technique if there are complications or a lack of progress. Obviously R-One procedure data collected for publication would need IRB approval for that step as with any research endeavor.

CONCLUSION

Minimally invasive surgery is currently established in urology. With the R-One platform, the technique can move towards further reductions in surgical access points with the capability to perform complex maneuvers in smaller spaces compared with multiport procedures.

In our report, we performed novel approaches for urological surgeries in a preclinical model demonstrating their feasibility. In addition, classic approaches were also reassessed and completed establishing the capability of the R-1. Surgeons embracing this technology should do so after adequate training, and objectively report their outcome using transparent methods. Prospective, multicenter studies will be needed as early adopters of this technology seek to push the boundaries of their skills set, adding the R-One platform to their surgical armamentarium.

SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.urology.2019.05.045.

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Supplementary Table 1. Initial Investigation using a Purpose-Built Single port Robotic System (SP1098) in a Pre-Clinical Model

Study	Approach	Surgery	Complication* & Conversion#
Maurice et al[2]	Retroperitoneal	Partial nephrectomy	None/None
Ramirez et al[18,19]	Perineal	Radical Prostatectomy and Pelvic lymph node dissection	None/None
Maurice et al[20]	Perineal	Radical cystectomy and extended pelvic lymphadenectomy	None/None
Garisto et al[21]	Perineal	Intracorporeal Ileal Conduit Urinary Divesion	None/None
Kaouk et al[22]	Transvesical	Partial Prostatectomy	None/None

* Complication defined as any accidental puncture or injury to adjacent organ.
# Conversion to standard open or robotic surgical approach.

Supplementary Table 2. Natural Orifice Transluminal Endoscopic Surgery (NOTES)

Author/Center	Year	Surgery/ No. Cases	Type	Approach	Complications	Comments
Branco et al[28]	2008	1 nephrectomy	Lap	Transvaginal hybrid NOTES	None	First report of hybrid NOTES nephrectomy performed in humans
Kaouk et al[29]	2009	1 nephrectomy	Lap	Transvaginal hybrid NOTES	None	Dense adhesions required use of an umbilical port
Sotelo et al[30]	2010	4 nephrectomies	Lap	Transvaginal hybrid NOTES	Rectal injury, failure to progress	Only one umbilical trocar was used in each patient

R-LESS, Robotic laparoendoscopic single site; Lap, laparoscopic; NOTES, Natural Orifice Transluminal Endoscopic Surgery.