〈Clinical Report〉

Robot-assisted laparoscopic radical prostatectomy - A report of our current robotic surgery -

Shinya UEHARA, Yoshiyuki MIYAJI, Tomohiro FUJII, Ryoei HARA, Yuhei HORIKAWA, Shohei TSUKIMORI, Hiroyasu TAKASAKI, Norifumi NISHISHITA, Atsushi NAGAI

Department of Urology, Kawasaki Medical School

ABSTRACT This report is an examination of the results of the initial 200 cases that underwent robot assisted laparoscopic radical prostatectomy (RALP) at Kawasaki Medical School General Medical Center in Okayama, Japan. Two hundred patients that had RALP using the da Vinci Xi Surgical System from August 2016 to October 2019 were examined retrospectively. The median age was 70 years old, and the median PSA was 7.65 ng/ml. 35% of the cases had received a previous abdominal surgery. RALP was performed on all the patients. The median surgery time was 237.5 minutes, the median console time was 173 minutes and the median amount of bleeding was 150 ml. There were no intraoperative blood transfusions, complications or anastomotic failures. Histopathological examination found pT2 in 73.0% of cases and pT3 in 26.5% with positive surgical margins in 10.3% and 50.9% of cases, respectively. There were 17 postoperative cases confirmed to have an inguinal hernia and 3 cases with an incisional hernia. Also, one case had postoperative bleeding from the trocar insertion site, which required hemostasis and a blood transfusion. Urinary continence rates three months after surgery was 76.6% and was 95.3% after twelve months. RALP is a safe and minimally invasive method, but there are aspects that require improvement such as the pT3 positive surgical margin rate and postoperative continence.

doi：10.11482/KMJ-E202046181 *(Accepted on November 18, 2020)*

Key words：Prostate cancer, Robot-assisted radical prostatectomy

INTRODUCTION

The da Vinci Surgical System is the most widely used surgical robotic system in the world. In the 20 years since being approved for clinical use by the American Food and Drug Administration in the year 2000 there have been more than 5,600 systems put into use worldwide.

In 2001, Binder *et al*. were the first in the world to perform RALP to treat prostate cancer[1)], and since then RALP has quickly spread to replace both

Corresponding author
Shinya Uehara
Department of Urology, Kawasaki Medical School, Kawasaki Medical School General Medical Center, 2-6-1 Nakasange, Kita-ku, Okayama, 700-8505, Japan
Phone : 81 86 225 2111
Fax : 81 86 232 8343
E-mail: uesinn0116@gmail.com

conventional open surgeries and other laparoscopic surgeries. The approval of the da Vinci S in 2009 in Japan was much later than in some other countries around the world, and RALP costs have been covered by Japanese National Health Insurance since 2012. Currently RALP is a major surgical technique.

At the Kawasaki Medical School General Medical Center, RALP using the da Vinci Xi Surgical System has been performed since August 2016, and 200 cases were performed by October 2019. In this report, the surgical results from those initial 200 cases were collected and compared with the clinical and pathological results of other published reports. Our surgical methods and procedures were assessed to be reasonable and appropriate based on the data published to date.

SUBJECTS AND METHODS

Two hundred patients underwent RALP at the Kawasaki Medical School General Medical Center in Okayama, Japan from August 2016 to October 2019 and their cases were examined retrospectively.

In principle, the indication for RALP was patients whose clinical stage was T1c-T3aN0M0, preferably with a performance status of 0 or 1. When patients had a cardiac disorder, intracranial disorder and/or were taking anticoagulant or antiplatelet drugs, the relevant physician was consulted. In general, many facilities halt the administration of anticoagulant and antiplatelet drugs before a RALP, but when the cessation of anticoagulants and/or antiplatelets is considered to be difficult, heparin is used to replace anticoagulants and aspirin replaces other antiplatelet medications. Glaucoma is often a contraindication for RALP at many facilities, but it is possible at our facility using a retroperitoneal approach in a mild Trendelenburg position so that intraocular pressure doesn't rise. Patients with a history of abdominal operations were not necessarily excluded from the surgical indication, and a retroperitoneal approach was considered and chosen on a case-by-case basis.

The surgical procedure used, with some revisions later added, was based on the technique reported by Patel *et al*[2]. Under general anesthesia, patients are placed in a supine steep Trendelenburg position with both arms laid directly against the sides of the torso. An incision is made above the navel, with the camera port inserted into the abdominal space under direct vision. After inflating the abdomen to 12 mmHg, three robot ports and two assistant ports are inserted (Fig. 1). The intra-abdominal pressure is lowered to 8 mmHg, and the patient is inclined to 25°. The patient cart was docked to the left of the patient. Monopolar curved scissors were used for the right arm, fenestrated bipolar forceps were used for the left arm, and ProGrasp forceps were used on the extra arm. At the time of suturing, both arms were switched to the large needle driver.

The peritoneum is incised along the medial umbilical ligament and the prevesical space is revealed, then the prostatic anterior fat is removed. While preserving the fascia of pelvic muscle, the endopelvic fascia is incised close to the puboprostatic ligament and the dorsal vein complex is ligated by the border of the prostate and the urethra.

If no cancerous tissue is found in the prostate base biopsy, separate the gland while preserving as much of the bladder neck as possible. Then the vas deference and the seminal vesicles are exposed and dissected. While moving the vas deference and the seminal vesicles ventrally, the location of the fold in the Denonvillier's fascia needs to be confirmed. When preserving the nerves, the posterior wall of the prostate is dissected at the ventral layer of the Denonvillier's fascia, while the posterior wall of the prostate is dissected at the layer of fat of the anterior wall of the rectum when not preserving the nerves.

When preserving the nerves, lateral pedicles are clipped with the Hem-o-lok clip (Weck Closure Systems, Research Triangle Park, NC), and when

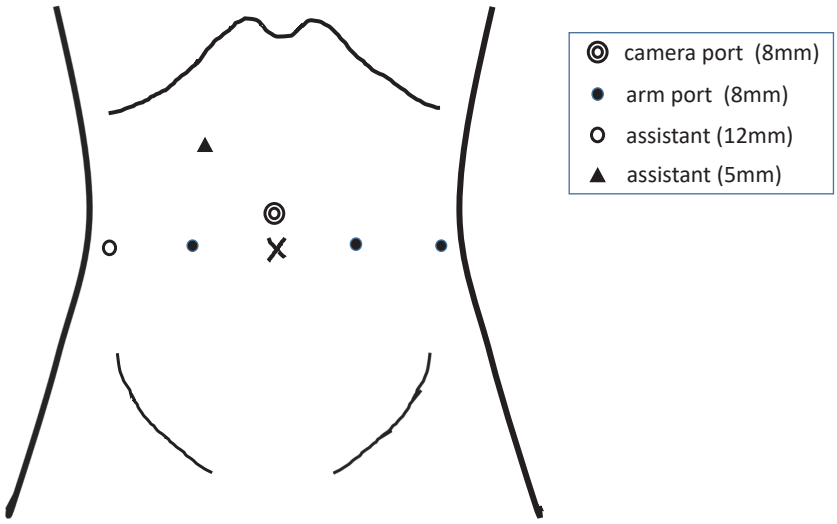

Fig. 1. Trocar's site

not preserving the nerves, the lateral pedicles are cut with a Ligasure Vessel Sealing System (Covidien, Boulder, Colo) or an electric knife. After setting the pneumoperitoneum pressure to 15 mmHg to avoid venous bleeding, the ligated dorsal vein complex is lifted ventrally to keep the border between the urethra and the prostate clear. The dorsal vein complex is divided away from the ligature and the anterior urethra is exposed and the margins of the dorsal vein complex are closed up with a continuous suture. After suturing, the pneumoperitoneum pressure is set back to 8 mmHg. If no cancerous tissues are found in the apex, the urethra is disconnected as proximally as possible to leave more urethral stump. The removed specimen is stored in an endopouch and lymph node dissection is performed after stanching the bleeding. The posterior reconstruction is done with two layers, followed by vesicourethral anastomosis and anterior reconstruction. The indwelling drainage catheter is left after undocking. The endopouch is retrieved after the patient is moved from the Trendelenburg position to a level position and the port opening is sutured.

To manage postoperative pain, fentanyl is continuously administered only during the operation day. The basic principle is to start walking and eating from the first day after surgery, to remove the drainage tube on the third day and the urethral catheter on the sixth day. Depending on the patient's condition, the schedule can be changed according to the decisions of the chief surgeon.

The cases were evaluated based on the patients' background, surgical results, pathological findings, postoperative complications and continence results.

The study protocol was approved by the Ethical Committee of Kawasaki Medical School (Approval No. 5012-00).

RESULTS

Of the RALPs performed between August 2016 to October 2019, 200 cases were deemed as suitable for evaluation. Table 1 indicates the patients' background. The ages ranged from 50 to 81 years old (median: 70 y.o.), the preoperative PSA was 2.8-98 ng/ml (median: 7.65 ng/ml). 70 cases (35%) had a history of abdominal surgery, but no cases required a conversion to laparotomy. 10 cases (0.5%) had glaucoma and 15 cases (7.5%) had a history of brain disease. 32 cases (16%) received preoperative

Table 1. Demographic data

No. of pts		200	
	median (range)		
Age, yrs	70 (50-81)		
Body Mass Index	24.1 (16.9-34.5)		
PSA (ng/ml)	7.65 (2.8-98.0)		
Prostate volume (cm^3)	28 (12-108)		
Previous abdominal surgery, pts		70	35.0%
	Appendectomy	32	16.0%
	Inguinal hernia	19	9.5%
	Cholecystectomy	10	5.0%
	Gastrectomy	7	3.5%
	Colectomy	2	1.0%
Previous hormonal therapy, pts		32	16.0%
Gleason score, pts	GS ≦ 6	38	19.0%
	GS = 7	74	37.0%
	GS ≧ 8	88	44.0%
Clinical stage, pts	T1c	30	15.0%
	T2a	54	27.0%
	T2b	50	25.0%
	T2c	53	26.5%
	T3a	13	6.5%
D'Amico risk stratification, pts	low	22	11.0%
	intermediate	56	28.0%
	high	122	61.0%

Table 2. Operative results

	median (range)		
Operation time, min	237.5 (172-345)		
Console time, min	173 (114-285)		
Blood loss including urine, ml	150 (20-900)		
Hemoblobin level, mg/dl			
pre-operative	14.6 (11.0-17.9)		
post-operative	12.6 (7.2-16.9)		
pre-to post-operative change	2.0 (0.2-4.7)		
Approach			
transperitoneal		182	91%
retroperitoneal		18	9%
Nerve sparing			
none		119	59.50%
bilateral		35	17.50%
unilateral		46	23%
Lymphnode dissection		51	25.50%
Intraoperative allogenic transfusion		0	0%
Intraoperative complications, pts		0	0%
Open conversion, pts		0	0%
Catheterization period, days	6 (5-9)		
urinary leakage		0	0%
Hospitalization period, days	10 (8-22)		

endocrine therapy for various reasons. The clinical diagnosis was T2 for 80% of the cases. D'Amico risk classification showed the majority (122 cases, 61%) were in the high-risk group.

Table 2 shows the surgical results. The surgery time ranged 172-345 minutes (median: 237.5 minutes), the console usage time was 114-285 minutes (median: 173 minutes) and blood loss

Table 3. Pathological results

		No. of pts	(%)	RM positive		
Pathological stage				overall	43	21.5%
pT2		146	73.0%		15	10.3%
	pT2a	24	12.0%		0	0.0%
	pT2b	16	8.0%		2	12.5%
	pT2c	106	53.0%		13	12.3%
pT3		53	26.5%		27	50.9%
	pT3a	35	17.5%		16	45.7%
	pT3b	18	9.0%		11	61.1%
pT4		1	0.5%		1	100.0%
Gleason score	GS ≦ 6	26	13.0%		3	11.5%
	GS =7	111	55.5%		18	16.2%
	GS ≧ 8	63	31.5%		22	34.9%

including urine varied 20-900 ml (median: 150 ml). A retroperitoneal approach was used in 18 cases (9.0%) due to a history of abdominal surgery, intracranial disease, or glaucoma. Bilateral nerve-sparing was performed in 35 (17.5%), unilateral in 46 (23.0%) and none in 119 cases (59.5%). No cases required a blood transfusion and there were no complications during surgery. The period of the catheterization was 5-9 days (median: 6 days), and the period of hospitalization was 8-22 days (median: 10 days). There were no cases in which anastomosis failure caused the extravasation of urine.

Table 3 shows the histopathological findings. There were 146 cases with pT2 (73.0%), 53 cases with pT3 (26.5%), and 1 case with pT4 (0.5%), with a positive surgical margin in 15 (10.3%), 27 (50.9%) and 1 case (100%), respectively. Among the pT2a cases there were no cases with a positive surgical margin. When compared with the patient's Gleason scores, the percentage of positive surgical margins rose along with the Gleason score. Lymph node dissection was done in 51 cases, with 5 of those cases being classified as pN1.

Table 4 shows postoperative complications. During observation, 17 patients developed an inguinal hernia and 3 patients developed an incisional hernia. Also, 2 patients had a wide range of subcutaneous bleeding a week after surgery. One patient had postoperative bleeding from the trocar insertion site, which required stanching and a blood transfusion.

Table 4. Postoperative complications

Inguinal hernia	17
Incisional hernia	3
Subcutaneous bleeding	2
Ileus	1
Intraabdominal bleeding	1
Lymphocele	1
wound infection	1
Chyle Leak	1

Table 5. Postoperative continence

1 month	44.9%	(89/198)
3 months	76.6%	(151/197)
6 months	90.3%	(178/197)
12 months	95.3%	(163/171)
Chyle Leak		1

※ Definition of continence: no pads or 1 pad per day (safety pad)

Table 5 shows the progress of postoperative continence. Continence was defined as requiring no pad or just one pad a day as a safety pad. The continence rates after surgery were 44.9% a month after surgery, 76.6% three months after surgery, 90.3% six months after surgery and 95.3% twelve months after surgery. A high continence rate was observed a year after the surgery even while a small number of patients continued to have severe incontinence.

DISCUSSION

RALP was approved and covered by the Japanese

National Health Insurance in 2012, and the types of robot-assisted surgeries performed in Japan in urology as well as in various other fields has been growing. Among urological robot assisted surgeries, a partial nephrectomy to treat kidney cancer was first approved in Japan in 2016, a total cystectomy in 2018 and pyeloplasty was approved in 2020.

At our facility from August 2016 to October 2019, 200 cases met the indications for RALP, and no cases needed to be switched to a different surgical method. The existing reports at the time stated that RALP could be safely performed on patients without damaging oncological or functional effects in patients with a history of abdominal surgery[3, 4]. Over a third (35%) of our patients had a history of abdominal surgery mainly for an appendicitis or an inguinal hernia, but none of them required a conversion to open surgery. RALP was safely performable just as the existing reports had described.

Another notable concern was the possibility that a steep Trendelenburg position can negatively affect a patients' circulatory dynamics, brain pressure and intraocular pressure[5]. Our patients with a history of glaucoma or intracranial diseases were 0.5% and 7.5%, respectively, and a retroperitoneal approach was chosen for those cases to avoid the steep Trendelenburg position. As a result, there were no postoperative problems related to glaucoma or intracranial disease, and it can be stated that RALP is not necessarily contraindicated even when patients have such a history. A meta-analysis by Tang *et al*[6]. stated a broad surgical time range of 140-280 minutes. Our surgical time range of 172-345 minutes (median: 237.5 minutes) tended to be a little longer than those previously published reports possibly due to the time taken to staunch and suture places that are bleeding. The use of a hemostatic agent could be one option to shorten our surgical time. The reported amount of intraoperative bleeding according to multiple reports was between 150 to 400 ml[6, 7], which is similar to our results of 20-900 ml (median: 150 ml). As a result, there were no cases that required an intraoperative blood transfusion. Our catheterization period was similar to published reports[8] and there were no cases of anastomotic failure, thus it can be concluded that our procedures and methods in those areas do not have problems either.

Tewari *et al*. reported[7] that the frequencies of intraoperative and perioperative complications were as follows: 0.9% requiring further surgeries, 0.8% with an intestinal obstruction, 0.7% with hematoma, 0.7% developing a wound infection, 0.3% with rectal damage, 0.3% developing deep vein thrombosis, 0.3% with a pulmonary embolism, 0.2% having a cardiac infarction, 0.09% with digestive system damage, 0.05% with pneumonia, and a 0.04% mortality rate. One of our cases had bleeding from the trocar insertion site after surgery and required another surgery. To minimize complications, careful attention is necessary to confirm that there is no bleeding or digestive tract damage. The published literature showed a small percentage (0.3%) with a pulmonary embolism caused by deep vein thrombosis, but this did not occur among our cases[7]. RALP with the da Vinci Xi Surgical System does not require patients to be in the lithotomy position, so fewer embolisms are likely to occur. However, it is still necessary to minimize possible risk factors such as attempting to shorten the surgical time and to avoid compression of pelvic veins by the system's instrument shafts. Our understanding is that lowering the intra-abdominal pressure as much as possible decreases the risk of deep vein thrombosis, therefore our procedure is to keep the pressure at 8 mmHg when possible.

Alder *et al*[9]. reported that the estimated incidence of inguinal hernia after RALP was 7.9% and intraoperative inguinal hernia prevention techniques significantly improved the inguinal hernia incidence.

In this report, 17 cases (8.5%) developed inguinal hernias within 3 years after surgery. As of now, we don't perform any procedure to prevent inguinal hernia because no reliable procedures exist. We should consider more reliable prevention techniques in the near future.

Past reports[6-8, 10, 11] stated a positive surgical margin in 8-12% of pT2 cases and around 40% in pT3 cases. Our pT3 cases had a higher percentage of positive surgical margin (50.9%). Preoperative MRIs and biopsies are used for tumor localization for pT3 cases and expanding the resection margin may reduce the incidence of positive surgical margin. Thus, the resection line should be adjusted to suit each case. The follow-up term in this report is short so biochemical recurrence was not examined but needs to be evaluated in the future along with further monitoring of our positive surgical margin rate.

Urinary continence in this report was defined as requiring no pad or just one pad a day as a safety pad. Alexander *et al*[8]. reported that 21.8% didn't use any pads a week after surgery and 30.9% used just a single pad, 78.4% didn't use any pads or only used a safety pad 3 months after surgery, and 90.3% didn't use any a year after surgery. Definitions of continence vary among professionals and different reports are very challenging to directly compare. That being said, our 12 months continence results seem to be equivalent to other published results, even though our early postoperative recovery seems comparatively worse. There are cases that do not regain continence even a year after surgery. In this report, only less than 50% of the cases underwent nerve-sparing, so actively choosing surgical methods such as bilateral nerve preservation or Retzius space preservation[12, 13] can begin to improve surgical results. If so, it is important to consider each case carefully and balance the methods that might reduce positive surgical margin with methods that might improve long-term incontinence.

In a report[8] that compared RALP and retropubic radical prostatectomies, RALP was proved to be superior in terms of intraoperative bleeding, blood transfusions and the period of urinary catheter indwelling, but there was no significant difference in terms of positive surgical margin or biochemical recurrence. The RALP group showed just a slight superiority in terms of urinary continence, and there was no difference in sexual function found between the two groups. In that report, the authors did not state that either method was superior, but instead concluded that the most important factor is the surgeon's skill.

Novara *et al*[11, 14]. reported that RALP was superior in terms of bleeding and blood transfusions but there was no difference between the two methods in terms of positive surgical margin. On the other hand, Tang *et al*[6]. reported that RALP is superior in terms of positive surgical margin, biochemical recurrence, and sexual function. These conflicting reports make it difficult to make a conclusion on superiority. Both surgical methods can indeed be effective if performed by a skillful surgeon. However, in Japan there are not a sufficient number of cases at many facilities that would allow a surgeon to become an experienced expert in retropubic radical prostatectomy. Recently RALP has been reported to have a shorter learning curve[15, 16], thus giving RALP an advantage to become the standard method in the future.

CONCLUSION

RALP has twenty years of history around the world and its surgical techniques have largely been standardized. However, there yet remain some issues to be solved such as frequent postoperative inguinal hernias, the necessity of extended pelvic lymph node dissection and refractory urinary incontinence. Although our experiences here had similar results to published reports, there are aspects of our techniques and methods that can be improved

in the future.

DISCLOSURES

The authors report no conflicts of interest related to this work.

REFERENCES

1) Binder J. and Kramer W: Robotically-assisted laparoscopic radical prostatectomy. BJU Int. 2001; 87: 408-410. doi: 10.1046/j.1464-410x.2001.00115.x.

2) Patel VR, Tully AS, Holmed R, Lindsay J: Robotic radical prostatectomy in the community setting-the learning curve and beyond: initial 200 cases. J Urol.2005; 174: 269-272. doi: 10.1097/01.ju.0000162082.12962.40.

3) Yumioka T, Iwamoto H, Masago T, Morizane S, Yao A, Honda M, Muraoka K, Sejima T, Takenaka A: Robot-assisted radical prostatectomy in an initial Japanese series: the impact of prior abdominal surgery on surgical outcomes. Int J Urol. 2015; 22: 278-282. doi: 10.1111/iju.12678.

4) Di Pierro GB, Grande P, Mordasini L, danuser H, Mattei A: Robot-assisted radical prostatectomy in the setting of previous abdominal surgery: Perioperative results, oncological and functional outcomes, and complications in a single surgeon's series. Int J Surg. 2016; 36: 170-176. doi: 10.1016/j.ijsu.2016.10.038.

5) Raz O, Boesel TW, Arianayagam M, Lau H, Vass J, Huynh CC, Graham SL, Varol C: The effect of the modified Z trendelenburg position on intraocular pressure during robotic assisted laparoscopic radical prostatectomy: a randomized, controlled study. J Urol. 2015; 193: 1213-1219. doi: 10.1016/j.juro.2014.10.094.

6) Tang, K, Jiang K, Chen H, Chen Z, Xu H, Ye Z: Robotic vs. Retropubic radical prostatectomy in prostate cancer: A systematic review and a meta-analysis update. Oncotarget. 2017; 8: 32237-32257. doi: 10.18632/oncotarget.13332.

7) Tewari, A, Sooriakumaran P, Bloch DA, Seshadri-Kreaden U, Hebert AE, Wiklund P: Positive surgical margin and perioperative complication rates of primary surgical treatments for prostate cancer: a systematic review and meta-analysis comparing retropubic, laparoscopic, and robotic prostatectomy. Eur Urol. 2012; 62: 1-15. doi: 10.1016/j.eururo.2012.02.029.

8) Haese A, Knipper S, Isbarn H, *et al.*: A comparative study of robot-assisted and open radical prostatectomy in 10790 men treated by highly trained surgeons for both procedures. BJU Int. 2019; 123: 1031-1040. doi: 10.1111/bju.14760.

9) Alder R, Zetner D, Rosenberg J: Incidence of Inguinal Hernia after Radical Prostatectomy: A systematic Review and Meta-Analysis. J Urol. 2020; 203: 265-274. doi: 10.1097/JU.0000000000000313.

10) Okegawa T, Omura S, Samejima M, Ninomiya N, Taguchi S, Nakamura Y, Yamaguchi T, Tambo M, Fukuhara H: Laparoscopic radical prostatectomy versus robot-assisted radical prostatectomy: comparison of oncological outcomes at a single center. Prostate Int. 2020; 8: 16-21. doi: 10.1016/j.prnil.2019.09.004.

11) Novara G, Ficarra V, Mocellin S, *et al.*: Systematic review and meta-analysis of studies reporting oncologic outcomes after robot-assisted radical prostatectomy. Eur Urol. 2012; 62: 382-404. doi:10.1016/j.eururo.2012.05.047.

12) Tai TE, Wu CC, Kang YN, Wu JC: Effects of Retzius-sparing on robot-assisted laparoscopic prostatectomy: a systematic review with meta-analysis. Surg Endosc. 2020; 34: 4020-4029. doi: 10.1007/s00464-019-07190.2.

13) Lim SK, Kim KH, Shin TY, Han WK, Chung BH, Hong SJ, Choi YD, Rha KH: Retzius-sparing robot-assisted laparoscopic radical prostatectomy: combining the best of retropubic and perineal approaches. BJU Int. 2014; 114: 236-244. doi: 10.1111/bju.12705.

14) Novara G, Ficarra V, Rosen RC *et al.*: Systematic review and meta-analysis of perioperative outcomes and complications after robot-assisted radical prostatectomy. Eur Urol. 2012; 62: 431-452. doi: 10.1016/j.eururo.2012.05.044.

15) Patel VR, Tully AS, Holmes R, Lindsay J: Robotic radical prostatectomy in the community-setting-the learning curve and beyond: initial 200 cases. J Urol. 2005; 174: 269-272. doi: 10.1097/01.ju.0000162082.12962.40.

16) Ahlering TE, Skarecky D, Lee D, Clayman RV: Successful transfer of open surgical skills to a laparoscopic environment using a robotic interface: initial experience with laparoscopic radical prostatectomy. J Urol. 2003; 170: 1738-1741. doi: 10.1097/01.ju.0000092881.24608.5e.