

# Impact of Fellowship Training on One-Year Outcomes of Robotic-Assisted Prostatectomy

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## ABSTRACT

**Background and Objectives:** We examined 1-year functional and oncologic outcomes for robotic-assisted laparoscopic prostatectomy (RALP) from a single surgeon entering practice directly from fellowship training.

**Methods:** We prospectively analyzed the first 100 RALPs performed by one fellowship-trained robotic surgeon. Data included resident involvement during the procedure, perioperative data, and surgical complications (scored using the Clavien grading system). Health-related quality of life (HRQOL) data were captured using the EPIC questionnaire at baseline (prior to surgery) and at 1-year follow-up.

**Results:** Eighty-two patients (82%) had hospital stays of 2 days or less without any postoperative complications, urethral catheter removal was within 14 days of surgery, and none required readmission to the hospital. The overall positive margin rate was 21% (19% for patients with T2 disease). Clavien grades 1 through 4 complication rates, respectively, were 4%, 10%, 1%, and 1%. There were no deaths, reoperations, or bladder neck contractures. One patient (1%) required a blood transfusion within the 90-day perioperative period. At 1-year follow-up, 78% of patients reported wearing no pads; 41.3% of patients with baseline and 1-year follow-up data reported having intercourse.

**Conclusions:** We provide baseline data pertaining to the morbidity, oncologic efficacy, continence results, and potency outcomes of new surgeons performing RALP.

**Key Words:** Robotics, Prostatectomy, Training, Prostatic neoplasms.

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## INTRODUCTION

The number of urologists incorporating robotic-assisted laparoscopic prostatectomy (RALP) into practice is steadily increasing. Related to this, the robotic training background of these urologists is becoming more varied and diverse as RALP continues to increase in utilization. Currently, the benchmark data for RALP are based on thousands of cases from experienced open or laparoscopic surgeons who have incorporated RALP into practice.<sup>1-5</sup> Currently, benchmark data are absent in the literature for trainees entering practice directly from residency or fellowship training.

In 2006, Rosser et al<sup>6</sup> examined pathologic outcomes and complication rates of the first open radical retropubic prostatectomies (RRP) performed by 2 oncology fellowship-trained surgeons. Their results provided benchmark data for new surgeons entering practice for the first time and also demonstrated that fellowship training could shorten the learning curve of RRP and lead to early results comparable to results of expert surgeons. Motivated by this, we completed a prospective evaluation of the first 100 RALP from a fellowship-trained robotic surgeon entering practice to examine pathologic results, complications rates, and 1-year functional outcomes. Our primary objective was to provide initial insight as to fellowship training in RALP and to provide the first benchmark data for other trainees entering practice (either out of fellowship or residency).

## MATERIALS AND METHODS

Following Institutional Review Board approval, we prospectively analyzed the first 100 RALPs performed by one surgeon (DDT) immediately following fellowship training. The surgeries were performed at a tertiary care institution that included a residency-training program. During fellowship training, the surgeon was directly involved in 58 RALP under the supervision of one experienced mentor, performing a portion of each of the operations and assisting during the remaining portions of the operation. The systematic integration of residents and fellows into the different steps of RALP in this long-running fellowship has previously been outlined.<sup>7</sup> This 1-year fellowship program was credentialed by the Endourological Society and rec-

ognized by the American Urologic Association. The surgeon had no RALP experience during residency but was involved in over 100 open radial retropubic prostatectomies during training.

### **Surgical Technique**

RALP was performed with a standard 3-arm da Vinci Surgical System (Intuitive Surgical, Sunnyvale, CA) in a similar manner to the original Vattikuti Institute procedure.<sup>8</sup> Abdominal access was gained with the Veress needle technique in the supra-umbilical mid-line. All cases were performed transperitoneally. The assistant ports were placed on the patient's right side. The dorsal vein was oversewn with 0 polyglactin suture. Nerve sparing was performed utilizing an athermal technique and nonabsorbable polymer surgical clips. The anastomosis was performed with double-armed 2-0 poliglecaprone sutures in a running van Velthoven fashion.<sup>9</sup>

All patients were placed on a pathway to be discharged on postoperative day 1 or 2. The surgical drain was removed directly before discharge, and urethral catheter removal was performed on postoperative day 10 to 14. Cystography was performed on the first 85 patients and then only when required.

### **Pathologic Analysis**

All surgical specimens were weighed and the external surface dipped in ink. The apex and bladder neck regions were amputated and sectioned perpendicular to the margin. The remaining specimen was sectioned at 5-mm intervals. A positive margin was defined as tumor at the inked margin upon microscopic assessment. Patients with tumor through the capsule were considered to have extracapsular extension.

### **Perioperative Outcomes**

Perioperative outcomes were derived from final pathological specimens and perioperative data. Blood loss, transfusion requirements, hospital stay, intraoperative complications, postoperative complications, and hospital readmissions were recorded. Hospital stay and surgical drains were considered prolonged if >2 days in duration. Catheter time was considered prolonged if in place >14 days. Primary Gleason score of  $\geq 4$  or a total Gleason score of  $\geq 8$  was used to define high-grade cancer. Surgical complications were scored using the Clavien grading system.<sup>10</sup>

### **Postoperative Outcomes**

All patients were seen at 4 months to 6 months and 1 year postoperatively. Only patients with both baseline data points and 1-year follow-up were analyzed. Data acquired at follow-up include PSA measurement, pads per day usage, and health-related quality of life (HRQOL) data as quantified by the EPIC questionnaire.<sup>11</sup> We defined an undetectable PSA as  $<0.15\text{ng/mL}$  and categorized continence status as "no pads ever," "1 pad per day," or "more than 1 pad per day" requirement.

We also analyzed single questions from EPIC to interpret surgical outcomes on continence and sexual function. We used question 27 ("How many pads or adult diapers per day did you use to control leakage during the last 4 weeks?") and question 63 ("During the last 4 weeks, how often did you have sexual intercourse?") respectively. Any response other than "none at all" to question 63 was affirmation of sexual potency.<sup>12</sup> All responses were linearly transformed to a scale of 0 to 100, with higher scores indicating better quality of life outcomes. A minimally important difference, or a lack of return to baseline HRQOL on EPIC scoring, was defined as greater than half a standard deviation from the preoperative baseline score.<sup>13</sup>

### **Statistical Analysis**

Continuous data are presented as a median with a range. Categorical data are presented as counts and percentages. Comparisons between patients with follow-up and patients without follow-up for categorical variables were completed using the Fisher exact test. Comparisons between patients with follow-up and patients without follow-up for continuous variables were completed using the Wilcoxon rank sum test. All statistical tests are 2-sided, the threshold of significance set at  $P=.05$ , and statistical analyses were performed using SAS software (SAS institute, Cary, North Carolina).

## **RESULTS**

The first 100 RALP were completed over a 26-month period. Preoperative data, intraoperative data, pathologic findings, and 30-day postoperative course were available for all 100 patients. No patients required reoperation within the 30-day postoperative period. Eighty-two patients (82%) had a hospital stay of  $\leq 2$  days without postoperative complications and had urethral catheter removal within 14 days of surgery and without readmission.

**Table 1** depicts patient characteristics and operative data. The surgical assistants were variable. A chief resident assisted on 45 of the cases and performed various portions of the operation, which were recorded. For the first 100 cases, the chief resident did not perform the apical dissection or nerve sparing. Pelvic lymph node dissection was completed on 31 patients without complication (mean 3.48 lymph nodes per dissection). One patient had positive pelvic lymph nodes. Twenty-four patients were noted to be high risk preoperatively as defined by PSA >10, primary Gleason score of  $\geq 4$ , or palpable disease. Twenty of 24 of these patients had pelvic lymph node dissections completed.

**Table 2** notes surgical pathology results and postoperative data. The overall positive margin rate was 21%. The margin rate of pathologic T2 patients was 19% (18 of 94). No clinical T1c Gleason 6 patients developed PSA recurrence over the 1-year follow-up period. A chief resident performed bladder neck dissection in 31 patients; none of these patients had positive basal margins. Both of the patients with positive bladder neck margins had seminal vesicle invasion on final pathologic examination. Nine patients had positive apical margins on final pathologic examination; 7 of these patients had an undetectable PSA at 1-year follow-up. Two of the 10 patients with a positive posterior margin had PSA recurrences within 1 year.

**Table 1.**  
Patient Characteristics and Operative Data

<b>Preoperative Data</b>	
Mean Age (years)	61.6 (45-75)
Mean BMI	27.2 (19-37.8)
Clinical Gleason	8-9 (9%)
PSA >10ng/mL	8 (8%)
Clinical Stage	
T1c-86	
T2-12	
T3-2	
Previous Abdominal Surgery (not including inguinal hernias)	27(27%)
Mean AUA Score	7.7
Preoperative Lupron	2 (2%)
Preoperative Blood Thinners	4 (4%)
<b>Operative Data</b>	
Assistant	
Chief Resident	45
Junior Resident	35
Physician Assistant	20
Median Lobe	12
Nerve Sparing	
Bilat	66
None	18
Unilat	16
PLND	31
Open Conversion	0%
Transfusion (90 days)	1%
Rectal Injury	0%

**Table 2.**  
Surgical Pathology and Postoperative Data

<b>Pathology</b>	
Mean size	49.9 g (30-88)
Gleason Scores	
3+3 =	41
3+4 =	44
4+3 =	10
$\geq 4+4 =$	5
Positive Margins	21 (21%)
Apex	9
Posterior	10
Bladder Neck	2
Pathologic Stage	
T2	94
T3a	3
T3b	3
<b>Postoperative Data</b>	
Hospital Stay	
$\geq 3$ days	3 (1 MI, 1 epigastric bleeding 1, ileus)
3 days	9 (6 Ileus, 1 bladder spasm, 1 dizziness, 1 awaiting transportation)
2 days	46
1 day	42
Hospital Re-admissions	5(5%)
Ileus	1(1%)
Epididymitis	1(1%)
Pelvic Pain/Hematoma	3(3%)
Prolonged (>14 days) catheter time	12 (12%)

**Table 3** lists the surgical complications based on the Clavien classification system of surgical complications. Twelve patients (12%) stayed in the hospital >2 days. Three patients remained in the hospital >3 days. One patient was noted to have a CVA on postoperative day #2 after CT imaging was performed for mild hand weakness. He was placed on anti-coagulation and had no residual effects.

One-year PSA follow-up was available on 97 patients. Eight patients had a detectable PSA within the 1-year follow-up period. Seven of these patients were  $\geq$  Gleason 7 on pathologic examination and 5 had positive surgical margins. Ninety-seven patients had data pertaining to continence at 1 year with 81 of 97 patients (83.5%) wearing no pads at the 1-year follow-up period, 10 patients having no regular leakage but wearing an insurance pad, and 6 patients (6.2%) requiring 1 pad or more per day. With regard to question 27 from EPIC (“How many pads or adult diapers per day did you use to control leakage

during the last 4 weeks?”), results were available for 46 patients. Thirty-six (78%) reported wearing no pads. Two patients (4%) reported wearing  $\geq 3$  pads per day.

With regard to question 63 from EPIC (“During the last 4 weeks, how often did you have sexual intercourse?”), responses were available for 46 patients. Nineteen of 46 patients (41.3%) reported sexual activity. Twenty-seven patients (59%) never had intercourse. Of those questioned with baseline and 1-year data available, 20 (65%) failed to reach their baseline sexual function. Interestingly, 15 of the 48 patients (31%) reported never having intercourse preoperatively.

Baseline and 1-year follow-up HRQOL data were available for 31 patients. In the urinary bother domain, 5 patients (17%) failed to get back to baseline scores. In the urinary incontinence domain, 17 patients (57%) failed to reach baseline function. The total urinary function score revealed 10 patients (34%) who failed to reach baseline scores. Twenty-two patients (73%) failed to reach baseline on total sexual function score. Only 4 patients (13%) failed to reach baseline total bowel function score.

**Table 3.**  
Complications

Clavien Grade I	4%
Anastomotic leak	4
Clavien Grade II	10%
Ileus	4
Pelvic Hematoma	2
Blood Transfusion	1
Epididymitis	1
UTI	1
UA	1
Clavien Grade III	1%
Pelvic Hematoma	1
Clavien Grade IVa	1%
Myocardial Infarction	1
Clavien Grade IVb	0
DVT	0
Wound Dehiscence	0
Wound Infections	0
Re-operations	0
Lymphocele	0
Bladder Neck Contracture	0
Rectal Injury	0
Enterotomy	0
Vascular Injury	0

## DISCUSSION

The number of cases required to overcome the “learning curve” and to reach “expert” status for RALP remains unclear. Related to this, a consensus definition of “expert” status is difficult given the complex nature of an operation that relies not only on surgical safety and oncologic cure, but also on long-term functional outcomes, including continence and potency. Previous investigators have reported that the number of cases required to overcome the “learning curve” for radical prostatectomy lies anywhere from 20 cases to 250 cases.<sup>14</sup> The majority of these investigators have focused primarily on a decrease in operative times and positive surgical margins as evidence that the learning curve has been overcome. Furthermore, most of the data pertaining to safety, surgical margins, and long-term functional outcomes of RALP are from early adopters of the technology. The surgeons in these studies generally have extensive open, laparoscopic, or robotic experience.<sup>1-5</sup> This underscores the current lack of baseline/benchmark data for RALP in the setting of new surgeons entering practice directly out of training.

Rosser et al<sup>6</sup> reviewed records of 66 men who underwent RRP performed by 2 fellowship-trained surgeons in their first year of practice. Their reported positive margin rate was 14%, and one intraoperative rectal injury occurred. Three patients developed pulmonary embolism postoper-

atively, and 6 patients developed postoperative bladder neck contractures. They concluded that RRP positive margin rates of fellowship trained surgeons compared favorably with those in large series reported by more experienced surgeons. This study focused on positive margin rates at the expense of long-term oncologic and functional follow-up; our study aims to provide the same data with regard to RALP, while including 1-year oncologic and functional outcomes.

The safety profile in this series is comparable to those in the literature of experienced robotic surgeons. The overall complication rate was 16% in our series with a majority of those being Clavien grade 1 and 2 (minor). No reoperations, bladder neck contractures, or peri-operative deaths occurred. No rectal injuries or enterotomies occurred. One patient (1%) received a blood transfusion secondary to a postoperative epigastric bleed that resolved with conservative measures. One Clavien grade 4a complication (an intraoperative MI) occurred and was successfully treated with angioplasty and stent placement followed by anticoagulation. This was the only patient who required ICU care. There was one Clavien grade 3 complication (pelvic hematoma causing pain) that required percutaneous drain placement. No wound complications (infections, hernias, or dehiscence) or symptomatic lymphoceles were noted. Two recent publications evaluated the complications of mature RALP series (2500 and 3317 patients).<sup>3,4</sup> The most common peri-operative complication in each series was urine leakage. In our series, 82% of the patients were discharged home within 2 days of surgery and had no complications, with their catheter being removed within 14 days of surgery. Of patients in the series of 3317 patients, 90.2% noted the same.<sup>4</sup>

Surgeons learning RALP note the vesicourethral anastomosis to be one of the most difficult portions of the operation to master.<sup>7,15</sup> Vesicourethral anastomosis takes longer for residents and fellows to gain proficiency with than any other portion of RALP.<sup>7</sup> Experienced open surgeons incorporating RALP into practice have a higher rate of prolonged catheterization compared to fellowship-trained robotic surgeons.<sup>16</sup> Twelve patients in this series (12%) had a catheter in place more than 14 days for various reasons including hematuria and anastomotic leak. In 4 patients, anastomotic leakage led to prolonged hospitalization (>2 days) and discharge to home with a drain in place. Of interest, 3 of the leaks requiring patients to go home with a drain in place occurred in the first 35 cases.

The overall positive margin rate in our experience was 21% with a 19% positive margin rate in those with patho-

logic T2 disease. RRP series have reported positive margins varying between 16% to 46%.<sup>17</sup> RALP positive margin rates reported in the literature range anywhere from 3% to 35%.<sup>1,3,5,16</sup> The common theme in most studies pertaining to prostate cancer margin positivity is that margins decrease with experience. Eight patients in our series had a detectable PSA within the 1-year follow-up period. Seven of these patients were  $\geq$ Gleason 7 on pathologic examination and 5 had positive surgical margins. Long-term follow-up is required to ensure a durable absence of PSA recurrence.

On direct questioning, 83.5% of patients required no pads at the 1-year follow-up period; 6.2% required one pad or more per day. These findings correlated with data of patients who answered EPIC question 27 at baseline and at the 1-year follow-up period. Pad-free continence of the highest volume robotic surgeon in the world is 96.3% at 12 months<sup>5</sup> with mean age of patients in that series being younger (57.8 years vs 61.6 years) with a lower mean BMI (28.3 vs 31.4). These factors have previously been associated with improved continence following prostatectomy.<sup>18</sup>

At 1-year follow-up, 41% of patients who completed the HRQOL questionnaire reported sexual activity; 65% of patients failed to reach their preoperative erection status. Variability in the literature on assessing sexual function and the varying definitions of potency make analysis of erectile function following prostate cancer surgery difficult. Interestingly, 31% of patients in the series reported no sexual function before surgery. It remains to be seen if increasing surgical experience or the addition of more advanced surgical systems (Si surgical system, 4th robotic arm) will improve postoperative erection status. Regardless, we believe it is essential to provide patients with a clear understanding of the potential sexual side-effects following RALP.

A confounding variable in this study is the incorporation of residents into the RALP of a fellowship-trained surgeon. Trainees were involved in 80% of the first 100 RALP. A chief resident assisted on 45 of the cases and performed various portions of the operation. For the first 100 cases, the chief resident did not perform any portion of the apical dissection or nerve sparing. The chief resident performed bladder neck dissection in 31 patients. None of these 31 operations accounted for the 2 patients with positive bladder neck margins on final pathology. Schroeck et al<sup>19</sup> demonstrated that trainee involvement in RALP under the guidance of an experienced mentor does not affect margin positivity or EBL. It has been demon-

strated that trainees also improve with experience with the most difficult portions of the operation to master being the anastomosis and the bladder neck dissection.<sup>7,19,20</sup> Robotic surgical simulators may play a role in the near future in eliminating the initial awkwardness of trainees at the console, which can only improve trainee and patient safety during the operation.<sup>14</sup>

This study has several limitations. The outcomes of only 1 surgeon are reported. No assessment is provided of a control group of residents who completed training and entered practice without doing a subspecialty fellowship. Moreover, only 31% of patients had baseline and 1-year follow-up EPIC questionnaires completed leading to a possible response bias in the data. Since analysis of these data, we have altered our systems to improve acquisition of baseline and follow-up QOL data. Our definition of potency utilizing question 63 of EPIC also leaves open the possibility that a person who attempts intercourse 10 times in 1 month and is only successful once would be defined as “sexually active.” The first 100 cases were performed with the standard 3-arm da Vinci surgical robot. We now perform the procedure with a 4-arm Si surgical system. It is unknown whether the addition of the fourth arm to the surgery or the use of the more advanced Si system will alter surgical safety and outcomes. A future avenue of study would be pooled data from fellowship-trained robotic surgeons and those who only complete residency to assess for surgical safety, oncologic control, and long-term functional outcomes.

There remains no standardized credentialing system to evaluate surgeon competency and safety with regards to robotic surgery.<sup>21</sup> Most medical malpractice claims surrounding robotic surgeries are secondary to systems malfunctions, and 75% of those arise intraoperatively.<sup>22</sup> The most common cause of these intraoperative systems malfunctions are due to inexperience or lack of technical competence with the instrumentation/surgical device.<sup>21,22</sup> The peri-operative safety profile provided in this study may suggest that fellowship training can advance the practice by cutting down on technical errors that may lead to costly malpractice claims for the physician and hospital.

## CONCLUSION

This study may provide benchmark baseline data for assessing the impact of fellowship training on the morbidity, oncologic efficacy, continence results, and potency outcomes of new surgeons performing RALP.

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