

# Strategies to optimize the performance of Robotic-assisted laparoscopic hysterectomy

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## Abstract

A hybrid technique of robot-assisted, laparoscopic hysterectomy using the ENSEAL<sup>®</sup> Tissue Sealing Device is described in a retrospective, consecutive, observational case series. Over a 45 month period, 590 robot-assisted total laparoscopic hysterectomies +/- oophorectomy for benign and malignant indications were performed by a single surgeon with a bedside assistant at a tertiary healthcare center. Patient demographics, indications for surgery, comorbidities, primary and secondary surgical procedures, total operative and surgical time, estimated blood loss (EBL), length of stay (LOS), complications, transfusions and subsequent readmissions were analyzed. The overall complication rate was 5.9% with 35 patients experiencing 69 complications. Mean (SD) surgery time, operating room (OR) time, EBL, and LOS for the entire cohort were 75.5 (39.42) minutes, 123.8 (41.15) minutes, 83.1 (71.29) millilitres, and 1.2 (0.93) days, respectively. Mean surgery time in the first year (2009) was 91.6 minutes, which declined significantly each year by 18.0, 19.0, and 24.3 minutes, respectively. EBL and LOS did not vary significantly across the entire series. Using the cumulative sum method, an optimization curve for surgery time was evaluated, with three distinct optimization phases observed.

In summary, the use of an advanced laparoscopic tissue-sealing device by a bedside surgical assistant provided an improved operative efficiency and reliable vessel sealing during robotic hysterectomy.

**Key words:** ENSEAL, hysterectomy, laparoscopy, robot-assisted, robotic, surgery.

## Introduction

Major advancements in minimally invasive surgery over the past three decades have expanded the applications to gynecologic surgery and improved most perioperative outcomes. Multiple studies have demonstrated that laparoscopic hysterectomy has lower perioperative morbidity than abdominal hysterectomy (Nieboer et al., 2012; Candiani and Izzo, 2010; Walsh et al., 2009; Summit et al., 1998) yet abdominal hysterectomy remains the most common approach for hysterectomy worldwide (Jacoby et al., 2009; Wright et al., 2013). Surgeons proficient in laparoscopic surgery have observed rapid recoveries and low complication rates associated

with minimally invasive surgery. However the universal adoption of laparoscopic surgery in gynecology has been slowed by challenges related to surgical skill, and operating room staff experience.

The introduction of robotic assistance with the da Vinci<sup>®</sup> Surgical System (INTUITIVE SURGICAL, Sunnyvale, CA, USA) approved by the Food and Drug Administration for gynecologic procedures in 2005 has helped to recruit more gynecologic surgeons to perform minimally invasive surgery. Robotic assistance has been reported to increase the adoption of laparoscopic hysterectomy due its improvements in surgeon ergonomics, 3D stereoscopic visualization, wristed 7 degree of freedom instruments, scaled motion, and improved surgeon

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control of multiple instruments (Hoekstra et al., 2009).

Debate has been raised regarding the value of robotics in gynecologic surgery regarding operating room time, technique, cost, and superiority compared to traditional laparoscopy. There has been a focus towards an “either/or” concept of laparoscopy versus robotic surgery. In fact, it has become increasingly apparent that robotics can be an adjunct to laparoscopy with great opportunity to combine the benefits of each approach (ACOG, 2009). The rise of “advanced energy” instruments has been integral in the advancement of endoscopic surgery. Although these advanced energy devices have been applied to laparoscopic devices, they have not been as successfully adopted to the robotic instrumentation.

Traditional teaching for robotic gynecologic surgery utilizes a center camera port, 2-3 robotic ports and an ancillary port used mostly for retraction, suction devices, and specimen removal. Vessel ligation is accomplished with the robotic bipolar grasper or more recently, with the robotic advanced bipolar vessel sealer, at institutions where this is available. An alternative technique combines the advantages of the robotic surgical platform with the flexibility of alternate advanced laparoscopic vessel sealing devices by a bedside surgical assistant for vessel ligation.

Smaller series or large database evaluations (Pasic et al., 2010; Lenihan et al., 2008; Payne and Dauterive 2008; Nezhad et al., 2006; Fiorentino et al., 2006) have been published regarding surgeon and institution experience and outcomes with robotic assisted laparoscopic hysterectomy. These have generally demonstrated the feasibility of robotic assistance with similar results as traditional laparoscopic surgery. The aim of the current study was twofold. First, this single surgeon, single institution, case series utilizing the hybrid technique of advanced energy instrumentation for vessel sealing with robotic surgery aimed to validate the safety and potential advantages of this technique as an alternative to traditional robotic surgery. Second, this study aimed to analyze the surgical efficiency and perioperative outcomes over time for a high-volume robotic surgeon and surgical team utilizing this approach.

## Methods and Materials

This study involved a collaboration between Baptist Health of South Florida and Ethicon Endo-Surgery as a retrospective, observational, consecutive case series. Research funding was received from ETHICON (Cincinnati, OH, USA); no additional

funding was received. From January 2009 to September 2012, 770 consecutive adult women with benign and malignant indications underwent laparoscopic, robot-assisted gynecologic surgery performed by a single surgeon (NL) at a single tertiary healthcare institution in the United States.

To minimize selection bias, prospectively determined inclusion criteria were applied to create a cohort that included all adult ( $\geq 18$  years old) women consecutively undergoing gynecologic surgery over a 45 month period at a single institution by the principal investigator (NL) using a robot-assisted laparoscopic technique in tandem with the ENSEAL® Tissue Sealing Device. No exclusion criteria were applied to ensure a heterogeneous “real world” population to facilitate the subsequent generalizability of the patient population. All surgical procedures were performed by a single surgeon (NL) at a tertiary, 452-bed hospital located in a major metropolitan region surrounding Miami, Florida USA that serves patients primarily from the US, Latin America, and the Caribbean.

Data were extracted from an electronic medical records (EMR) database that was secured and maintained in compliance with institutional privacy and data security standards. The data set included patient demographics, indications for surgery, comorbidities, primary and secondary surgical procedures, operating room time (defined from wheels in to wheels out) and surgical time (defined from initial skin incision to final suture), estimated blood loss (EBL), length of stay (LOS), and complications (evaluated utilizing ICD-9 coding), transfusion information and subsequent readmissions. Complications presenting after discharge were assessed only if resulting in a readmission. Surgery time was defined as the duration in minutes between the initial incision to close of the final suture (i.e., skin to skin). Using surgery time as a surrogate marker for surgeon and operative team proficiency, cumulative summation (CUSUM) analysis was applied to the entire case series. This study was reviewed and approved by an institutional review board (IRB) prior to initiation and was performed in compliance with the Health Insurance Portability and Accountability Act (HIPAA) and Good Clinical Practices (GCPs).

## Surgical Technique

### 1. Abdominal Entry

Access to the abdomen in all cases was performed with the “direct entry” technique using a 12 mm ENDOPATH® XCEL® Dilating Tip Trocar (ETHICON, Inc., Cincinnati, OH, USA). For patients with large midline scars from prior surgery,

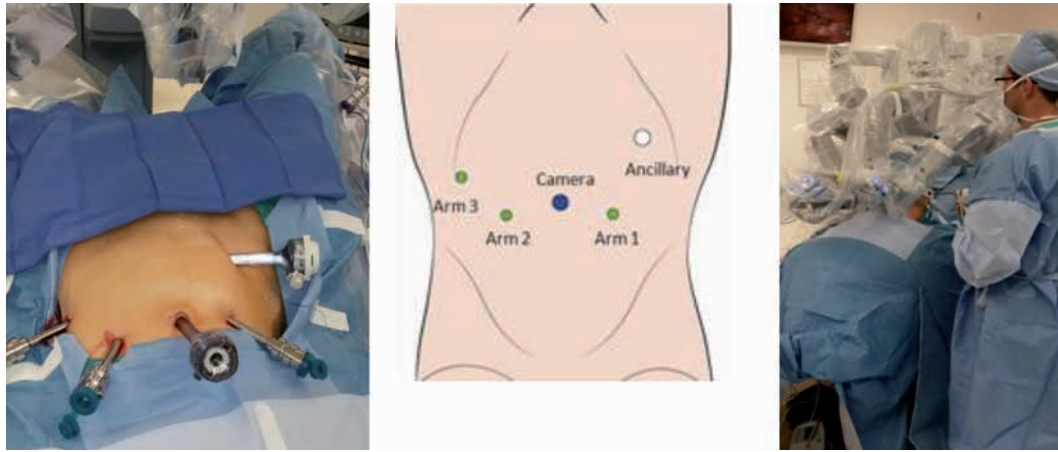


Fig. 1. — Port Placement and Surgical Assistant

the initial incision was made superior to the umbilicus via the same approach. Occasionally an open Hassan technique was performed for more complex abdomens.

## 2. Trocar Placement

The primary surgeon employed a 5-port technique for robotic surgery. After abdominal entry through the umbilicus for the camera port, the patient was then positioned into steep Trendelenburg position. Figure 1 illustrates trocar placement. With the primary surgeon positioned on the patient's left side, the surgical assistant placed the 8mm reusable metal trocar into the right abdomen (robotic arm #1) followed by the placement of the ancillary port (5 or 12 mm trocar) into the right lower quadrant. The primary surgeon then placed the left abdominal 8 mm metal trocar (robotic arm #2) and left flank trocar (robotic arm #3). After trocar insertion, the DaVinci robot was docked and all instruments advanced under direct visualization: *ProGrasp*<sup>TM</sup> Forceps (INTUITIVE SURGICAL, INC., Sunnyvale, CA, USA) placed through robotic arm #3 was used to manipulate the uterus throughout the surgery. Cardier Forceps (INTUITIVE SURGICAL, INC.) (robotic arm #2) and Hot Shears<sup>TM</sup> (Monopolar Curved Scissors) (INTUITIVE SURGICAL, INC.) (robotic arm #1) were utilized for tissue dissection. The umbilical 12 mm trocar was the camera port using a 0 degree Intuitive camera. The camera port site was placed superior to the umbilicus only in cases where a large midline scar was present or for very large uteri.

## 3. Vessel Sealing

A hallmark of this technique was the synergy between the primary surgeon using the robotic

platform and the assisting surgeon using laparoscopic instrumentation primarily, but not exclusively through the ancillary port. The primary surgeon maintained position at the da Vinci surgical console to perform all tissue manipulation, dissection and presentation of vessels. The surgical assistant maintained position at bedside where ENSEAL was employed through the ancillary port for the right uterine vessels and bilateral ovarian vessels. When approaching the left uterine vessels, the robotic grasper in robotic arm #2 was removed and the ENSEAL was “telescoped” through this trocar for direct access to the left uterine vessels.

## 4. Uterine Manipulation

A uterine manipulator was not used throughout this series; a “sponge stick” technique (ring-forcep with Raytech) handled by the surgical assistant was employed to apply pressure to the anterior vagina for the initial colpotomy. Uterine manipulation was performed in all cases by the primary surgeon using the *ProGrasp* Forceps (robotic arm #3).

## 5. Vaginal Closure

Vaginal closure was performed with robotic instruments in all cases. Early in the series, a two-layered closure with 0-Vicryl was used including one running layer followed by interrupted sutures using intracorporeal knot tying. Later in the series, a two-layered closure with 0 V-Loc<sup>TM</sup> Absorbable Wound Closure Device composed of a copolymer of glycolic acid and trimethylene carbonate (Covidien, Mansfield, MA, USA) was the preferred method.

## Statistical analysis

All variables collected were summarized using descriptive statistics including counts and

percentages for categorical variables, and mean, standard deviation or standard error, median, minimum, and maximum for continuous variables.

The impact of categorical baseline characteristics, pre-operative diagnosis categories, and secondary procedures on the outcome variables of surgery time, operating room time, EBL, and LOS was assessed using Analysis of Variance. Patients were also categorized based on the number of medical comorbidities present using an index derived from the Elixhauser comorbidity variables and categorized based on the number of select medical comorbidities present (Wright et al., 2013).

Surgery time, operating time, EBL, and LOS were summarized overall and by operative year. Comparisons between 2009 and each successive year were performed using the Wilcoxon Rank Sum test. Analysis of Variance was also performed as a sensitivity analysis.

The cumulative sum (CUSUM) method was used to evaluate an optimization curve for surgery time. This method was based on calculating the running total of the difference between each surgery time and the mean of all surgery times. Phases of the learning curve were estimated graphically by plotting the CUSUM for each surgery time against the case number and then determining the minimum value on the plot. Summary statistics were provided for surgery time, operating time, EBL, and LOS for the observations included in each respective optimization curve phase. To understand the impact that case complexity may have had on the optimization curve, the incidence of adhesiolysis or enterolysis,

lymphadenectomy, and uterine morcellation intra-operatively was estimated in each phase. Additionally, the distribution of Elixhauser comorbidity scores (0, 1,  $\geq 2$ ) was summarized for each phase. Comparisons between CUSUM phases for continuous variables were performed using an Analysis of Covariance model with terms for Phase and comorbidity index and for categorical variables using the Chi-square test. All between group comparisons were performed in a post-hoc manner using a nominal significance level of 0.05. No adjustments were made for multiple comparisons. Analyses were performed with SAS version 9.3 (SAS Institute, Inc., Cary, NC).

## Results

During a 45 month period between January 2009 and September 2012, 770 consecutive laparoscopic, robot-assisted laparoscopic gynecologic surgical procedures for benign and malignant indications were performed. The following groups were excluded from analysis: 79 adnexal surgeries without hysterectomy, 63 other primary surgeries, 23 radical Wertheim hysterectomies, and 4 supracervical hysterectomies. Robotic total hysterectomies with lymph node staging for endometrial cancer were included in the analysis. Most [601 (78.1%)] of the procedures performed during the study period were total laparoscopic hysterectomies including bilateral or unilateral salpingo-oophorectomy as indicated. All procedures satisfying the prospective eligibility criteria are characterized in Table I.

**Table I.** — Original Cohort Procedure Profile by Indication for Surgery.

<b>Total Patients (N = 770)</b>	<b>n (%)</b>
<b>Laparoscopic Robot-Assisted Hysterectomy</b>	<b>628 (81.6)</b>
Total laparoscopic hysterectomy +/- USO/BSO <sup>1</sup>	601(78.1)
Total laparoscopic hysterectomy with BSO	488 (63.4)
Total laparoscopic hysterectomy only	112 (14.5)
Total laparoscopic hysterectomy with USO	1 (0.13)
Radical hysterectomy	23 (3.0)
Supracervical hysterectomy	4 (0.5)
<b>Laparoscopic Robot-Assisted Salpingectomy and Oophorectomy</b>	<b>79 (10.3)</b>
Salpingo-oophorectomy	72 (9.4)
Oophorectomy	5 (0.6)
Salpingectomy	2 (0.3)
<b>Other Primary Surgeries</b>	<b>63 (8.2)</b>
Myomectomy	36 (4.7)
Cystectomy	9 (1.2)
Debulking	7 (0.9)
Miscellaneous ( $\leq 2$ )	11 (1.4)

<sup>1</sup>BSO = Bilateral salpingo-oophorectomy, USO = Unilateral salpingo-oophorectomy.

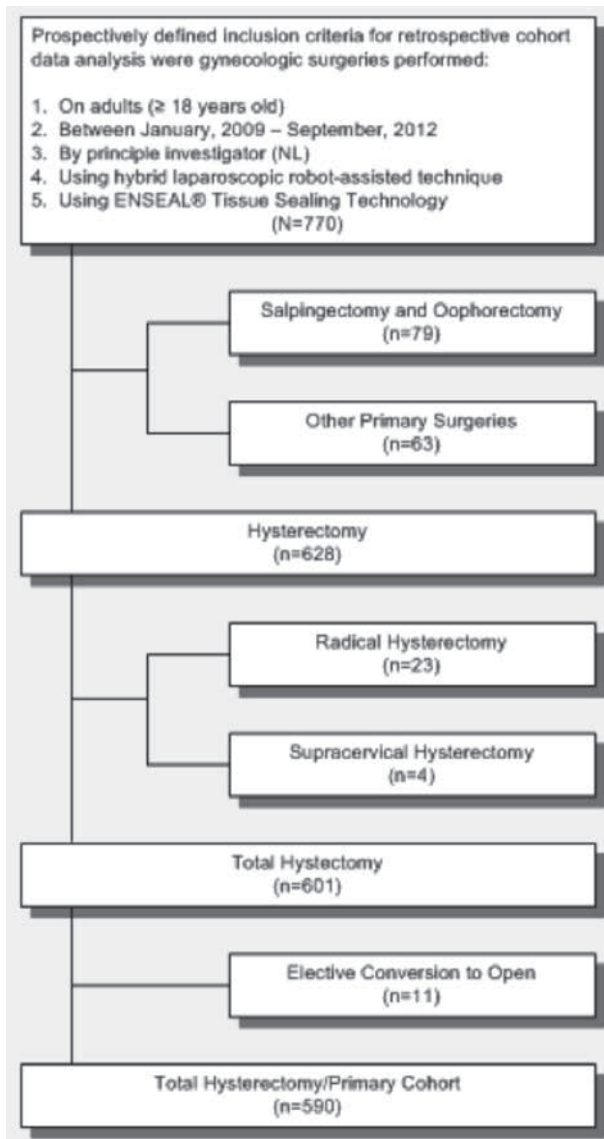


Fig. 2. — Participant Flow Diagram

Eleven (1.4%) total laparoscopic hysterectomies were electively converted to an open approach based upon surgeon determination of feasibility at the time of initial laparoscopic inspection of the abdomen. This included dense adhesions prohibiting safe visualization, carcinomatosis, or uterine size in rare instances.

Figure 2 illustrates the participant flow applied to derive the primary cohort for analysis. After removing the 11 procedures electively converted to an open approach, 590 (76.6%) patients comprised the primary cohort for all subsequent analyses. This cohort was comprised of adult women ranging between 30-92 years of age with a mean (SD) age of 51.8 (10.6) years. Most patients were between the ages of 41-50 [250 (42.4%), Hispanic [299 (50.7%)], married [374 (63.4%)], with commercial (private) insurance [469 (79.5%)]. The cohort primarily consisted of patients with benign pathologies.

Table II. — Indications for Surgery and Comorbidity Score.

Total patients (N = 590)	n (%)
<b>Benign Indication</b>	<b>459 (77.8)</b>
<b>Benign Neoplasms</b>	<b>263 (44.6)</b>
Uterine leiomyomas	231 (39.2)
Ovary/Adnexa	30 (5.1)
Cervix	1 (0.2)
Genital organs, unspecified	1 (0.2)
<b>Non-Inflammatory Disorders</b>	<b>56 (9.48)</b>
<b>Endometriosis</b>	<b>39 (6.61)</b>
<b>Abnormal Bleeding</b>	<b>37 (6.27)</b>
<b>Inflammatory Disorders</b>	<b>11 (1.86)</b>
<b>Prolapse</b>	<b>4 (0.7)</b>
Other	<b>49 (8.3)</b>
<b>Malignant Indication</b>	<b>103 (17.5)</b>
Uterus	79 (13.4)
Ovary/Adnexa	12 (2.0)
Cervix	5 (0.8)
Other (Breast, Bone, Skin)	7 (1.2)
<b>Carcinoma In Situ (n = 28)</b>	<b>28 (4.7)</b>
<b>Comorbidity Score</b>	
0	250 (42.4)
1	173 (29.3)
$\geq 2$	167 (28.3)

Indications for surgery and comorbidity scores are summarized in Table II.

No deaths were reported in this series. The overall complication rate was 5.9%, 35 patients experiencing 69 complications. Organ injury was observed in 2 (0.3%) patients with 1 (0.2%) intraoperative uterine artery injury with hemorrhage and 1 (0.2%) post-operative unidentified ureteral injury requiring readmission to the hospital within 31-60 days. Although 3 (0.5%) postoperative fevers were reported; only 1 (0.2%) infection was observed in the entire series requiring the patient for readmission to the hospital within 15-30 days. Other complications observed after discharge that required readmissions to the hospital included urinary obstruction requiring ureteral stent [1 (0.2%)] and inflammatory conditions such as acute appendicitis [1 (0.2%)], and vaginal cuff abscess [1 (0.2%)]. Intraoperative hemorrhagic events included hematoma complicating the surgery [2 (0.3%)] and acute post-hemorrhagic anemia [1 (0.2%)]. Vaginal cuff dehiscence was reported for 2 (0.3%) patients and 2 (0.3%) thromboembolic events including acute deep vein thrombosis [1 (0.2%)] were observed.

Mean surgery time was greatest in the first year of the series, but declined each subsequent year.

**Table III.** — Univariate impact of preoperative diagnoses and secondary procedures.

	<b>Surgery Time (min)</b>	<b>OR Time (min)</b>	<b>Estimated Blood Loss (ml)</b>	<b>Length of Stay (days)</b>
<b>Pre-Operative Diagnoses</b>				
<b>Adhesions</b>	<b>Mean (SE)</b>	<b>Mean (SE)</b>	<b>Mean (SE)</b>	<b>Mean (SE)</b>
Yes (n = 93)	<b>86.8 (4.06)<sup>1</sup></b>	<b>135.0 (4.24)<sup>1</sup></b>	83.1 (8.47)	1.34 (0.10)
No (n = 497)	<b>73.4 (1.76)<sup>1</sup></b>	<b>121.7 (1.83)<sup>1</sup></b>	83.1 (3.57)	1.23 (0.04)
<b>Cancer</b>				
Yes (n = 103)	<b>92.8 (3.81)<sup>1</sup></b>	<b>144.1 (3.95)<sup>1</sup></b>	84.8 (8.13)	1.36 (0.09)
No (n = 487)	<b>71.3 (1.79)<sup>1</sup></b>	<b>119.5 (1.82)<sup>1</sup></b>	82.7 (3.60)	1.22 (0.04)
<b>Diabetes</b>				
Yes (n = 36)	77.9 (6.58)	127.9 (6.86)	78.9 (13.73)	1.47 (0.15)
No (n = 554)	75.4 (1.68)	123.5 (1.75)	83.3 (3.39)	1.23 (0.04)
<b>Endometriosis</b>				
Yes (n = 210)	72.0 (2.72)	<b>119.2 (2.83)<sup>2</sup></b>	82.4 (5.44)	<b>1.13 (0.06)<sup>2</sup></b>
No (n = 380)	77.5 (2.02)	<b>126.3 (2.11)<sup>2</sup></b>	83.4 (4.13)	<b>1.31 (0.05)<sup>2</sup></b>
<b>Elixhauser Comorbidity Index</b>				
0 (n = 250)	70.9 (2.47)	118.0 (2.57)	79.0 (5.07)	1.21 (0.06)
1 (n = 173)	74.0 (2.97)	121.1 (3.08)	86.5 (6.10)	1.16 (0.07)
2+ (n = 167)	<b>84.1 (3.03)<sup>1</sup></b>	<b>135.2 (3.14)<sup>1</sup></b>	85.7 (6.12)	<b>1.38 (0.07)<sup>2</sup></b>
<b>Secondary Procedures</b>				
<b>Adhesiolysis and Enterolysis</b>	<b>Mean (SE)</b>	<b>Mean (SE)</b>	<b>Mean (SE)</b>	
Yes (n = 43)	<b>89.2 (5.99)<sup>1</sup></b>	<b>136.7 (6.26)<sup>2</sup></b>	<b>121.7 (13.12)<sup>1</sup></b>	1.44 (0.14)
No (n = 547)	<b>74.5 (1.68)<sup>1</sup></b>	<b>122.8 (1.75)<sup>2</sup></b>	<b>80.5 (3.36)<sup>1</sup></b>	1.23 (0.04)
<b>Lymphadenectomy</b>				
Yes (n = 38)	<b>93.0 (6.36)<sup>1</sup></b>	<b>148.2 (6.60)<sup>1</sup></b>	75.9 (13.73)	1.37 (0.15)
No (n = 552)	<b>74.3 (1.67)<sup>1</sup></b>	<b>122.1 (1.73)<sup>1</sup></b>	83.5 (3.39)	1.24 (0.04)
<b>Morcellation</b>				
Yes (n = 77)	<b>86.7 (4.47)<sup>1</sup></b>	<b>134.8 (4.67)<sup>1</sup></b>	78.9 (13.73)	1.17 (0.11)
No (n = 513)	<b>73.9 (1.73)<sup>1</sup></b>	<b>122.1 (1.81)<sup>1</sup></b>	83.3 (3.39)	1.26 (0.04)

<sup>1</sup> p < 0.02; <sup>2</sup> p < 0.05 for between group comparison.

Operating room time followed similar trends. Details regarding surgery time, OR time, blood loss and LOS are listed in table IV. The greatest EBL was reported at the beginning of the series in 2009, but no statistical differences were observed during any subsequent year. Median (mean) LOS for the entire series was 1.0 (1.24) days and did not vary significantly across the entire series. After an overnight stay in the hospital, 87.3% and 5.6% of the patients were discharged on postoperative day 1 and 2 respectively with 7.1% being discharged between postoperative day 3 and 11.

Table III summarizes the impact that various preoperative diagnoses and secondary procedures had on surgery time, operating time, EBL, and LOS.

Figure 3.1 presents the CUSUM<sub>ST</sub> analysis which plots the cumulative sequential differences between each data point and the process average over time

(Bokhari et al., 2011; Lenihan et al., 2008) for the 590 consecutive surgical procedures. The CUSUM<sub>ST</sub> for this cohort was observed to consist of three (3) differentiated phases. Interphase comparison of surgery time, EBL, LOS, preoperative diagnoses, secondary procedures, and comorbidity scores are presented in Figure 3.2. Detailed summary statistics by year (overlapping individual phases) are represented in table IV.

## Discussion

This observational case series is the largest single surgeon consecutive series on robotic total hysterectomy using ENSEAL tissue sealing technology as the vessel sealer. Over the study period, 590 patients underwent robotic total hysterectomy for benign and malignant conditions. The overall median

Fig. 3.1. — CUSUM Plot – Optimization Curve Phases.

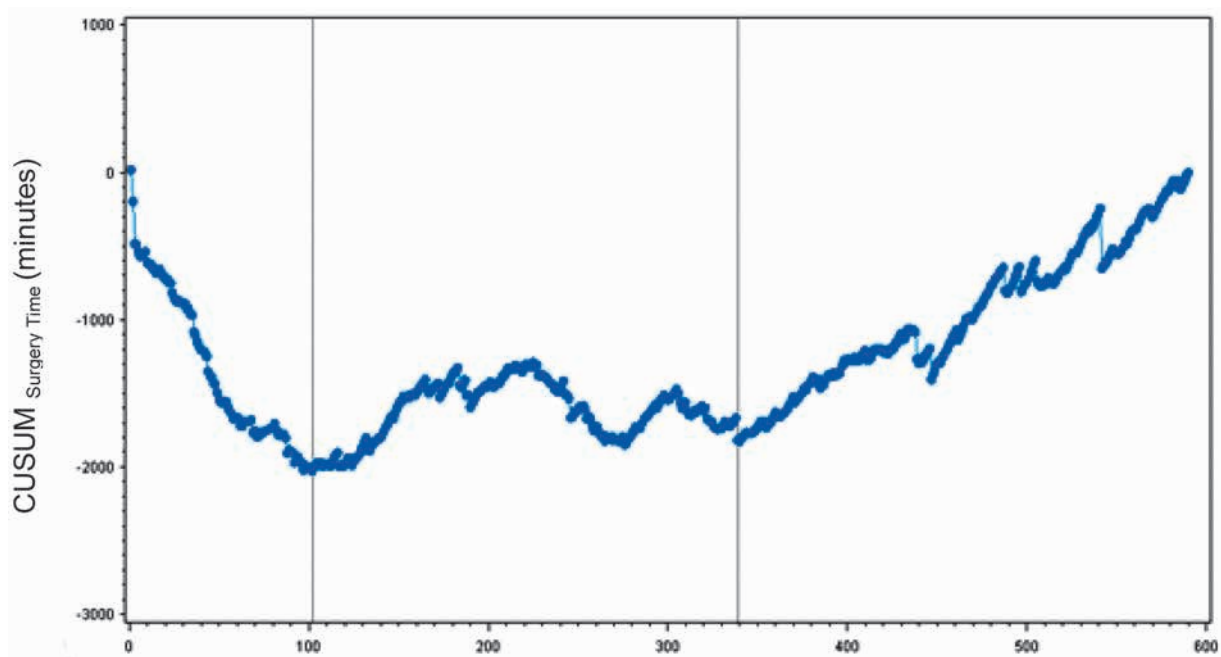


Fig. 3.2. — Interphase Comparison.

Parameter	Optimization Curve Phases		
	Phase I (n = 102)	Phase II (N = 236)	Phase III (n = 252)
<b>Outcomes [mean (SE)]</b>			
Surgery time (min)	94.2 (3.76)	<b>74.1 (2.46)*</b>	<b>69.4 (2.39)*</b>
Operating room time (min)	143.3 (3.87)	<b>124.3 (2.54)*</b>	<b>115.4 (2.46)*</b>
Blood loss (ml)	80.4 (7.67)	79.7 (5.23)	87.4 (5.08)
Length of stay	1.27 (0.09)	1.28 (0.06)	1.20 (0.06)
<b>Secondary Procedures [n (%)]</b>			
Adhesiolysis and enterolysis	0 (0.0)	<b>14 (5.9)*</b>	<b>29 (11.5)*</b>
Lymphadenectomy	8 (7.8)	22 (9.3)	8 (3.2)
Morcellation	0 (0.0)	<b>41 (17.4)*</b>	<b>36 (14.3)*</b>
<b>Elixhauser Comorbidity Index [n (%)]</b>			
Category 0	35 (34.3)	98 (41.5)	117 (46.4)
Category 1	35 (34.3)	72 (30.5)	66 (26.2)
Category ≥2	32 (31.4)	66 (28.0)	69 (27.4)
* p-value ≤ .0120 for comparison to Phase 1.			

Fig. 3. — Cumulative Summation Analysis – Optimization Curve

[range (mean)] surgery time in this cohort was 66 minutes [33, 483 (76)]. A significant decrease in the median surgery time was observed over the 45 months evaluated from 82 [42, 363 (91.57)] minutes in 2009 to 55 [34, 483 (67.24),  $p \leq .0005$ ] in 2012. These times compare favorably to most publications reporting on robotically assisted hysterectomies to date. In a similar retrospective, single surgeon, cohort study, JF Lin et al. reported a

median surgery time of 127 minutes performed for benign indications exclusively (Lin et al., 2013). A multi-center retrospective study by Payne et al. demonstrated a median (mean) surgery time of 145 (151) minutes in a total of 250 patients. Stratified within this same cohort, median (mean) surgery times for patients with a uterine weight < 500 grams and ≥ 500 grams were reported as 126 (133) minutes and 167 (174) minutes respectively (Payne et al.,

**Table IV.** — Summary Statistics.

Outcome	Time by Year				
	Overall (n = 590)	2009 (n = 124)	2010 (n = 164)	2011 (n = 158)	2012 (n = 144)
<b>Surgery time (min)</b>					
Mean	75.54	91.57	<b>73.55<sup>1</sup></b>	<b>72.59<sup>1</sup></b>	<b>67.24<sup>1</sup></b>
SD	39.42	42.13	30.49	30.03	50.18
Median	66.00	81.50	<b>66.00<sup>2</sup></b>	<b>65.50<sup>2</sup></b>	<b>55.00<sup>2</sup></b>
Minimum	33.00	42.00	39.00	33.00	34.00
Maximum	483.00	363.00	204.00	260.00	483.00
<b>Operating room time (min)</b>					
Mean	123.78	140.87	<b>124.05<sup>1</sup></b>	<b>119.33<sup>1</sup></b>	<b>113.63<sup>1</sup></b>
SD	41.15	42.74	33.20	31.81	51.54
Median	114.50	130.50	<b>114.50<sup>2</sup></b>	<b>114.00<sup>2</sup></b>	<b>100.00<sup>2</sup></b>
Minimum	72.00	78.00	76.00	75.00	72.00
Maximum	522.00	400.00	257.00	304.00	522.00
<b>Blood loss (ml)</b>					
Mean	83.07	84.03	78.43	90.54	78.55
SD	71.29	62.03	65.90	81.53	72.72
Median	50.00	66.00	50.00	50.00	50.00
Minimum	0.00	39.00	0.00	0.00	5.00
Maximum	500.00	204.00	400.00	500.00	500.00
<b>Length of stay (days)</b>					
Mean	1.24	1.27	1.30	1.17	1.24
SD	0.93	0.80	0.96	0.72	1.17
Median	1.0	1.0	1.0	1.0	1.0
Minimum	1.0	1.0	1.0	1.0	1.0
Maximum	11.0	7.0	8.0	8.0	11.0

1 =  $p \leq .0005$  by Analysis of Variance for comparison to 2009 ; 2 =  $p < 0.0001$  by Wilcoxon Rank Sum test for comparison to 2009.

2010). Paraiso et al., in a randomized controlled trial, reported mean surgery time of 173 minutes in the robot-assisted group compared to 103 minutes in the laparoscopic group of subjects undergoing hysterectomy for benign indications (Paraiso et al., 2013).

This study reports on the outcomes of an optimal surgical environment including a high-volume surgeon experienced in robotic surgery (over 200 cases prior to this reported series), a dedicated surgical assistant with equivalent robotic experience, a dedicated surgical team and a hospital supportive of robotic-specific training for staff. Although not specifically reported, docking times were inconsequential (less than 5 minutes) since these cases were performed well past a learning curve. There were several differences in surgical technique within this series in comparison to other reported robotic surgical techniques for gynecologic surgery that may

contribute to the optimization of surgical efficiency. Each of these modifications likely contributed to taking minutes off of each step and reducing the overall surgery and operating room times. A synergy was developed between primary surgeon and surgical assistant throughout the procedure. Rather than depend upon the assistant for control of the uterine manipulation, the primary surgeon preferred to maintain control of all aspects of tissue manipulation and anatomical positioning, while allowing the assistant to control application of the vessel sealer. This technique allowed for a seamless flow between each surgical step. Verbal communication between primary surgeon and assisting surgeon decreased over the series of cases as experience increased. The bedside assistant maintained the majority of communication with the surgical technician and nurse to ensure each instrument, suture, product or device was readily available for each anticipated



step of the procedure. This allowed the surgeon to truly immerse in the surgical technique. The surgical “team” approach promoted focus for each person in the operating room.

To analyze the impact of this team approach and the evolution of operative efficiency, cumulative sum analysis (CUSUM) methods were applied for quantitative assessment of the optimization curve based on surgery time enabling the ability to evaluate trends in performance not discernible by other methods of analysis (Bokhari et al., 2011). The CUSUM technique has been applied to the evaluation of innovative and advanced laparoscopic surgical techniques including the da VinciAZ robot and advanced bipolar tissue sealing devices (Woelk et al., 2013; Yim et al., 2013; Jiménez-Rodríguez et al., 2013; Williams et al., 2011; Papanna et al., 2011). Across the entire case series, an optimization curve using CUSUM methodology was observed to consist of three (3) differentiated phases. Phase I was the early phase characterized by surgery times consistently greater than the mean surgery time of the entire cohort. The surgical team was actively communicating and learning to work together. Phase II of the optimization curve was characterized by surgical times predominantly lower than the mean surgery time of the case series. Phase III illustrated system maturity and was characterized by the synergistic combination of individual expertise. Across each phase, as more complicated cases were introduced into the cohort, surgery time continued to trend lower without meaningful differences in EBL or LOS. Similarly, Payne et al., observed continued improvements in efficiency across hundreds of patients by reporting a mean surgery time of 119 minutes after initial implementation of a robotics program (Payne and Dauterive, 2008) for a consecutive case series of 100 patients, and 79 minutes for a subsequent cohort of another 100 consecutive procedures (Payne and Dauterive, 2010).

The observation that significant improvements in efficiency can be achieved even beyond the learning curve, (as measured by a reduction in surgery and operating room times), warrants further discussion. Surgical volume and its impact on outcomes remains a controversial topic. In bariatric surgery it has been proposed that higher volume is a “marker for quality” rather than a direct cause; the authors also implied that high-volume hospitals may have facilities and processes in place that promote improved outcomes (Liu et al., 2003). In benign gynecology, the positive impact of higher surgical volumes on outcome and morbidity has been demonstrated for hysteroscopic myomectomies and abdominal hysterectomies (Betjes et al., 2009; Han-

stede et al., 2009). A similar relationship has been established in other fields of surgery, e.g. orthopedics, neurosurgery and urology (Browne et al., 2009; Taub et al., 2004). It would therefore seem appropriate to expect a similar effect of volume in robotically assisted gynecologic surgery. Of course, surgery times are not the sole measure of proficiency; perioperative morbidity and recovery are, from a patients’ perspective, at least as important. The observed total adverse event rate of 5.9% in this series compares favorably to a recently reported adverse event rate of 12% for laparoscopic hysterectomies in a large Finish cohort (Mäkinen et al., 2013) and a robotic hysterectomy cohort for benign gynecologic disease reporting an overall complication rate of 5.5% (Wright et al., 2013). Another study reported that a change in operative practices over a ten year period (1996-2006) led to decreased total complication rates from 22% to 12% (Mäkinen et al., 2013).

Strengths of this study are in its single-surgeon, single-institution design which eliminates the variability in studies using multiple surgeons and/or institutions. Additionally, the large sample size and consecutive enrolment allowed for control of temporal effects of changes in surgical technique and approach. Limitations of the study include the lack of generalizability given the single-surgeon experience and narrow geographic and demographic representation of the cohort. Study data was extracted from EMRs not initially intended for research purposes. Consequently, the study lacked a number of factors such as body mass index and uterine weight and does not include long term follow-up. Finally, it must be noted that the study was funded by the manufacturer of the ENSEAL® tissue sealing technology. However, the risk of bias was minimized by use of robotic technology, and data extraction was based on data entered into the EMR system independent of the study.

Enabling technologies such as robotics and advanced tissue sealing devices continue to offer the surgeon an opportunity to evolve surgical techniques and impact perioperative outcomes. In the current study the use of an advanced laparoscopic tissue-sealing device by an experienced surgical team as the primary vessel sealer for robotic hysterectomy appears safe and may contribute to improved operative efficiency. This adds to the collective data on the safety and favorable patient outcomes of robotic hysterectomy. Moreover, these findings characterize an alternate approach that may appeal to surgeons interested in integrating the bedside surgical assistant into the process of maximizing surgical efficiency. Although this series demonstrates the feasibility of a hybrid technique

leveraging an advanced energy device during a robotically assisted procedure, the role of robotics as a minimally invasive option in the treatment algorithm of patients who warrant a hysterectomy remains to be determined.

## References

- ACOG technology assessment no. 6: Robot-assisted surgery. *Obstet Gynecol.* 2009;114:1153-5.
- Betjes HE, Hanstede MM, Emanuel MH et al. Hysteroscopic myomectomy and case volume hysteroscopic myomectomy performed by high- and low-volume surgeons. *J Reprod Med.* 2009;54:425-8.
- Bokhari MB, Patel CB, Ramos-Valadez DI et al. Learning curve for robotic-assisted laparoscopic colorectal surgery. *Surg Endosc.* 2011;25:855-60.
- Browne JA, Pietrobon R, Olson SA. Hip fracture outcomes: does surgeon or hospital volume really matter? *J Trauma.* 2009;66:809-14.
- Candiani M, Izzo S. Laparoscopic versus vaginal hysterectomy for benign pathology. *Curr Opin Obstet Gynecol.* 2010;22:304-8.
- Fiorentino RP, Zepeda MA, Goldstein BH et al. Pilot study assessing robotic laparoscopic hysterectomy and patient outcomes. *J Minim Invasive Gynecol.* 2006;13:60-3.
- Hanstede MM, Wise LA, Stewart EA et al. The relation of annual surgeon case volume to clinical outcomes and resource utilization in abdominal hysterectomy. *J Reprod Med.* 2009;54:193-202.
- Hoekstra AV, Jairam-Thodla A, Rademaker A et al. The impact of robotics on practice management of endometrial cancer: Transitioning from traditional surgery. *Int J Med Robot.* 2009;5:392-7.
- Jacoby VL, Autry A, Jacobson G et al. Nationwide use of laparoscopic hysterectomy compared with abdominal and vaginal approaches. *Obstet Gynecol.* 2009;114:1041-8.
- Jiménez-Rodríguez RM, Díaz-Pavón J M, De La Portilla DeJuan F et al. Learning curve for robotic-assisted laparoscopic rectal cancer surgery. *Int J Colorectal Dis.* 2013;28:815-21.
- Lenihan Jr JP, Kovanda C, Seshadri-Kreaden U. What is the learning curve for robotic assisted gynecologic surgery? *J Minim Invasive Gynecol.* 2008;15:589-594.
- Lin JF, Frey M, Huang JQ. Learning curve analysis of the first 100 robotic-assisted laparoscopic hysterectomies performed by a single surgeon. *Int J Gynaecol Obstet.* 2013;pii: S0020-7292(13)00502-X. doi: 10.1016/j.ijgo.2013.06.036. [Epub ahead of print]
- Liu JH, Zingmond D, Etzioni DA et al. Characterizing the performance and outcomes of obesity surgery in California. *Am Surg.* 2003;69:823-8.
- Mäkinen J, Brummer T, Jalkanen J et al. Ten years of progress-improved hysterectomy outcomes in Finland 1996-2006: a longitudinal observation study. *BMJ Open.* 2013;28;3(10): e003169. doi: 10.1136/bmjopen-2013-003169.
- Nezhat C, Saberi NS, Shahmohamady B et al. Robotic-assisted laparoscopy in gynecological surgery. *JSLs.* 2006;10:317-20.
- Nieboer TE, Hendriks JC, Bongers MY et al. Quality of life after laparoscopic and abdominal hysterectomy: a randomized controlled trial. *Obstet Gynecol.* 2012;119:85-91.
- Papanna R, Biau J, Mann LK et al. Use of the learning CurveCumulative summation test for quantitative and individualized assessment of competency of a surgical procedure in obstetrics and gynecology: Fetoscopic laser ablation as a model. *Am J Obstet Gynecol.* 2011;204:218.e1-218.e9.
- Paraiso MF, Ridgeway B, Park AJ et al. A randomized trial comparing conventional and robotically assisted total laparoscopic hysterectomy. *Am J Obstet Gynecol.* 2013;208:368.e1-7. doi: 10.1016/j.ajog.2013.02.008.
- Pasic RP, Rizzo JA, Fang H et al. Comparing robot-assisted with conventional laparoscopic hysterectomy: Impact on cost and clinical outcomes. *J Minim Invasive Gynecol.* 2010;17:730-8.
- Payne TN, Dauterive FR. A comparison of total laparoscopic hysterectomy to robotically assisted hysterectomy: Surgical outcomes in a community practice. *J Minim Invasive Gynecol.* 2008;15:286-91.
- Payne TN, Dauterive FR. Robotically assisted hysterectomy: 100 cases after the learning curve. *Journal of Robotic Surgery.* 2010;4:11-7.
- Payne TN, Dauterive FR, Pitter MC et al. Robotically assisted hysterectomy in patients with large uteri: Outcomes in five community practices. *Obstet Gynecol.* 2010;115:535-42.
- Summit RI, Stovall TG, Steege JF et al. A multicenter randomized comparison of laparoscopically assisted vaginal hysterectomy and abdominal hysterectomy in abdominal hysterectomy candidates. *Obstet Gynecol.* 1998;92:321-6.
- Taub DA, Miller DC, Cowan JA et al. Impact of surgical volume on mortality and length of stay after nephrectomy. *Urology.* 2004;63:862-7.
- Walsh CA, Walsh SR, Tang TY et al. Total abdominal hysterectomy versus total laparoscopic hysterectomy for benign disease: a meta-analysis. *Eur J Obstet Gynecol Reprod Biol.* 2009;144:3-7.
- Williams AK, Chalasani V, Martínez CH et al. Cumulative summation graphs are a useful tool for monitoring positive surgical margin rates in robot-assisted radical prostatectomy. *BJU Int.* 2011;107:1648-52.
- Woelk JL, Casiano ER, Weaver AL et al. The learning curve of robotic hysterectomy. *Obstet Gynecol.* 2013;121:87-95.
- Wright J, Herzog T, Tsui J, Ananthe C et al. Nationwide trends in the performance of inpatient hysterectomy in the United States. *Obstet Gynecol.* 2013;122:233-41.
- Yim GW, Kim SW, Nam EJ et al. Learning curve analysis of robot-assisted radical hysterectomy for cervical cancer: Initial experience at a single institution. *J Gynecol Oncol.* 2013;24:303-12.