GYNECOLOGY

Learning curve of robot-assisted laparoscopic sacrocolpo(recto)pexy: a cumulative sum analysis

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BACKGROUND: Determination of the learning curve of new techniques is essential to improve safety and efficiency. Limited information is available regarding learning curves in robot-assisted laparoscopic pelvic floor surgery.

OBJECTIVE: The purpose of this study was to assess the learning curve in robot-assisted laparoscopic pelvic floor surgery.

STUDY DESIGN: We conducted a prospective cohort study. Consecutive patients who underwent robot-assisted laparoscopic sacrocolpopexy or sacrocolporectopexy were included (n=372). Patients were treated in a teaching hospital with a tertiary referral function for gynecologic/multicompartment prolapse. Procedures were performed by 2 experienced conventional laparoscopic surgeons (surgeons A and B). Baseline demographics were scored per groups of 25 consecutive patients. The primary outcome was the determination of proficiency, which was based on intraoperative complications. Cumulative sum control chart analysis allowed us to detect small shifts in a surgeon's performance. Proficiency was obtained when the first acceptable boundary line of cumulative sum control chart analysis was crossed. Secondary outcomes that were examined were shortening and/or stabilization of surgery time (measured with the use of cumulative sum control chart analysis and the moving average method).

RESULTS: Surgeon A performed 242 surgeries; surgeon B performed 137 surgeries (n=7 surgeries were performed by both surgeons). Intraoperative complications occurred in 1.9% of the procedures. The learning curve never fell below the unacceptable failure limits and stabilized after 23 of 41 cases. Proficiency was obtained after 78 cases for both surgeons. Surgery time decreased after 24—29 cases in robot-assisted sacrocolpopexy (no distinct pattern for robot-assisted sacrocolporectopexy). Limitations were the inclusion of 2 interventions and concomitant procedures, which limited homogeneity. Furthermore, analyses treated all complications in cumulative sum as equal weight, although there are differences in the clinical relevance of complications.

CONCLUSION: After 78 cases, proficiency was obtained. After 24—29 cases, surgery time stabilized for robot-assisted sacrocolpopexy. In this age of rapidly changing surgical techniques, it can be difficult to determine the learning curve of each procedure. Cumulative sum control chart analysis can assist with this determination and prove to be a valuable tool. Training programs could be individualized to improve both surgical performance and patient benefits.

Key words: CUSUM, learning curve, robot-assisted surgery, sacrocolpopexy, sacrocolporectopexy

The arrival of robot-assisted laparoscopic surgery strongly affected surgical approaches to treat apical prolapse.[1] This has also impacted training in gynecologic surgery by broadening the surgical education that is required.[2] With the rising implementation of new techniques, standardization of self-teaching programs and quality-control measurements are very much needed to assess safety and optimize patient outcomes. Evaluation of learning curves allows for more accurate detection of potential pitfalls and could improve surgical training. Cumulative sum control chart (CUSUM) analysis has been shown to evaluate surgical performance efficiently by detecting small shifts in the parameters of a process,[3,4] which results in the visualization of trends that would not be detectable with other techniques. CUSUM analysis can be used as self-monitoring tool or to compare results with numbers from the literature. The analysis can mark phases in which complications arise, thereby warning the surgeon to change the training program or add additional training. A limitation of the CUSUM procedure is that it may signal a change not only in surgical failure rate but also in the referral pattern. An increased proportion of high-risk patients could be reason for a rise in complication rate, rather than a change in surgical performance.[3] This must be examined before training is adjusted.

The objective of this study was to use CUSUM analysis to examine the learning curve of robot-assisted laparoscopic sacrocolpopexy (RASC) for experienced laparoscopic surgeons. This could help determine the best format of structured training programs for laparoscopic surgeons to incorporate robot-assisted surgery safely and efficiently.

Material and Methods

All patients were treated in 1 large teaching hospital with a tertiary referral function for patients with gynecologic prolapse. Consecutive patients who underwent RASC or robot-assisted laparoscopic sacrocolporectopexy (RSCR) in case of multicompartment prolapse were included. If the uterus was present, a subtotal hysterectomy was performed concomitantly. Surgical techniques and materials have been described in detail previously.[5,6] All procedures were performed with the aid of the da Vinci Si-HD system (Intuitive Surgical, Inc, Sunnyvale, CA). Pneumoperitoneum

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AJOG at a Glance

Why was this study conducted?
With the rising implementation of new techniques, investigation of the learning curve and standardization of self-teaching programs are needed to assess safety and to optimize patient outcomes. This study was conducted to assess the learning curve of experienced conventional laparoscopic surgeons in robot-assisted laparoscopic sacrocolpopexy and sacrocolporectopexy.

Key findings
The procedures described were performed by 2 surgeons. Proficiency, based on intraoperative complications, was determined with the aid of cumulative sum analysis in which small shifts in surgical performance can be detected. Proficiency was obtained after 78 cases. Surgery time, which was established with cumulative sum analysis and moving average method, dropped earlier between 24−29 cases in robot-assisted laparoscopic sacrocolpopexy (no distinct pattern for sacrocolporectopexy).

What does this add to what is known?
Cumulative sum analysis could prove to be a useful tool in training programs that are set up for new robot-assisted medical devices to determine robotic proficiency.

was created through a Veress needle or Hasson open entry. Placement of two 12-mm and three 8-mm robotic trocars followed (intraabdominal pressure 12 mm Hg). Patients were placed in the lithotomy and Trendelenburg positions. The peritoneum was incised to reveal the promontory and to create an anterior vesicovaginal and posterior rectovaginal space. The mesh (Prolene; weight 80−85 g/m^2; Ethicon Inc, Johnson & Johnson, Hamburg, Germany) was sutured distally with nonabsorbable sutures to the posterior and anterior vaginal wall and the vaginal cuff or cervix. The 2 meshes were configured intracorporeally to a Y-shape. The posterior mesh was attached proximally to the sacral promontory with titanium tacks (Autosuture Protack 5 mm; Covidien, Minneapolis, MN). In case of RSCR, the colorectal surgeon started the procedure by performing a ventral mesh rectopexy according to the procedure described by Van Iersel.[6] In this case, no separate second mesh was placed directly on the posterior vaginal wall; the ventral rectopexy mesh was sutured on the anterior side to the posterior vaginal wall. The peritoneum was closed over the graft with a V-Loc suture (Covidien).

Surgical details of the procedures from the start of the use of robot-assistance until 4 years later were evaluated prospectively. Surgeries were performed by 2 gynecologists: "surgeon A" and "surgeon B." Surgeon A had 17 years of conventional laparoscopic experience, and surgeon B had 21 years of experience at the starting point. They had each performed approximately 300 laparoscopic sacrocolpopexy procedures. Before using robot assistance, surgeons and their surgical team followed a robotic learning course on cadavers. They had no previous robotic experience. The first 2 robotic cases that were performed were supervised by an urogynecologist who was experienced in RASC. No other robot-assisted surgeries that could have influenced the learning curve were performed by the surgeons in the study period.

The primary outcome measure was the determination of proficiency. The determination of proficiency was based on intraoperative complications, crossing ≥1 acceptable boundary lines of the CUSUM analysis. A secondary outcome was stabilization of surgery time to a steady state.

CUSUM analysis was performed to detect differences in the surgeon's performance and to determine proficiency.[4] Results were put into a graph, in which the X-axis represented the number of procedures, and the Y-axis represented the cumulative sum of success and failure. With each success, the graph will rise by "s"; with each failure, the graph will fall by "1-s." "S" is dependent on predetermined acceptable and unacceptable failure rates (Appendix). Acceptable failure rate was set at 4.4%, which was based on prospective or randomized controlled trials that described RASC and intraoperative complications (n=14/321).[7−11] Unacceptable failure rate was set at 2 times the acceptable failure rate (8.8%). When there were no intraoperative complications, the CUSUM graph increased by s=0.064 (Appendix). When a complication arose, the graph fell by 0.936 (1−s). Boundary lines were calculated to determine whether the surgical performance was acceptable (H_1) or unacceptable (H_{-1}).[4,12] Crossing >1 boundary line was also possible (H_2/H_{-2}, H_3/H_{-3}, etc), gaining either more skills (H_2/H_3) or falling further behind (H_{-2}/H_{-3}). With the aid of these multiple boundary lines, the CUSUM graph can also alert surgeons when they first perform acceptably, but then, for some reason, their performance rate decreases. The probability of falsely stating that the surgeon's performance is "acceptable" or "unacceptable" is called a type 1 error (α) and type 2 error (β). In this study. 10% type 1 and 2 errors was considered acceptable. When performing in the acceptable zone, a surgeon's performance is considered to be significantly better than the acceptable rate, with a false positive rate of α. Proficiency was obtained when the graph crossed H_1. Proficiency could be lost by crossing 2 (or more) unacceptable boundary lines. When the graph maintains between H_1 and H_{-1} (ie, circles round the 0-line) performance does not improve or deteriorate significantly, and neither null-hypothesis is rejected.

CUSUM analysis was also performed to detect differences in total surgery time. CUSUM analysis was used as a self-assessment tool. The mean surgery time per surgeon was calculated. This value was used as a reference value. When a surgery took more or less time than the mean surgery time, the graph would rise or fall with the absolute difference, respectively. Robotic setup time, console time, and

TABLE 1
Baseline characteristics and surgical details

Variable	Total (N=372)[a]	Surgeon A (n=242)	Surgeon B (n=137)	*P* value[b]
Age, y[c]	60.5±11.3	60.2±11.3	61.1±11.3	.424
Body mass index, kg/m^2 [d]	26.4±3.9	26.3±3.8	26.6±4.2	.572
Parity, n[d]	3.0 (0–11)	3.0 (0–6)	3.0 (0–11)	.364
Postmenopausal, n (%)	296 (79.6)	190 (78.5)	112 (81.8)	.299
Diabetes mellitus, n (%)	30 (8.1)	17 (7.0)	13 (9.5)	.393
Active smoker, n (%)	67 (18.0)	45 (18.6)	23 (16.8)	.787
American Society Of Anesthesiologists grading				.854
1	135 (36.3)	89 (36.8)	49 (35.8)	
2	200 (53.8)	130 (53.7)	74 (54.0)	
3	19 (5.1)	11 (4.5)	8 (5.8)	
Not reported	18 (4.8)	12 (5.0)	6 (4.4)	
Previous pelvic organ prolapse/incontinence surgery, n (%)[e]				.836
None	210 (56.5)	138 (57.0)	78 (56.9)	
1	123 (33.1)	79 (32.6)	45 (32.8)	
2	31 (8.3)	21 (8.7)	10 (7.3)	
≥3	8 (2.1)	4 (1.7)	4 (2.9)	
Other abdominal surgery, n (%)[f]	181 (48.7)	117 (48.3)	66 (48.2)	.974
Simplified pelvic organ prolapse quantification[d]				
Ba	3.0 (1–4)	3.0 (1–4)	3.0 (1–4)	.336
Bp	2.0 (1–4)	2.0 (1–4)	2.0 (1–4)	.878
C	3.0 (1–4)	3.0 (1–4)	3.0 (1–4)	.004[g]
D	2.0 (1–4)	2.0 (1–4)	2.0 (1–4)	.764
Type of surgery, n (%)				.132
Robot-assisted sacrocolpopexy	184 (49.5)[a]	129 (53.3)	62 (45.2)	
Robot-assisted sacrocolporectopexy	188 (50.5)	113 (46.7)	75 (54.7)	
Concomitant surgery, n (%)				
Subtotal hysterectomy	228 (61.3)	147 (60.7)	81 (59.1)	.827
Tension-free vaginal tape	19 (5.1)	12 (5.0)	8 (5.8)	.812
Anterior colporrhaphy	22 (5.9)	6 (2.5)	16 (11.7)	<.0005[g]
Posterior colporrhaphy	5 (1.3)	3 (1.2)	2 (1.5)	.595[h]
Oophorectomy	19 (5.1)	16 (6.6)	3 (2.2)	.058
Salpingectomy	122 (32.8)	88 (36.4)	36 (26.3)	.044[g]
Other	11 (3.0)	6 (2.5)	5 (3.6)	.536[h]

Pearson's Chi squared test, independent samples *T*-test, Mann-Whitney *U* test were used for categoric data, mean values, and median values, respectively, unless otherwise specified.

[a] Seven surgeries performed by both surgeon A and surgeon B; scores do not add up; [b] Comparing surgeon A with surgeon B; [c] Data are presented as mean±standard deviation; [d] Data are presented as median (range); [e] In case ≥2 pelvic organ prolapse/incontinence procedures were combined during 1 surgery, this was counted as 1 pelvic organ prolapse/incontinence surgery; [f] Abdominal surgery included in previous pelvic organ prolapse/incontinence surgery are not included; [g] Statistically significant; [h] Fisher's exact test (>20% expected count <5).

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total surgery time were also analyzed with the use of a moving average method (MOA). In MOA, big fluctuations are filtered out. The mean duration of the first 10 surgery times is point 1; mean duration of surgery 2–11 is point 2, etc.

The procedures were scored sequentially, based on operation date and time. Data were divided into groups of 25

TABLE 2
Intraoperative complications (Satava classification)[5]

Variable	Grade 1[a]	Grade 2[b]	Grade 3[c]	Total, n (%)	Conversion
Surgeon A	0	5[d]	0	5 (2.1)	0
Surgeon B	0	1[e]	1[f]	2 (1.5)	1
Total	0	6	1	7 (1.9)	1

[a] Incidents without consequences; [b] Incidents repaired intraoperatively; [c] Incidents requiring reoperation; [d] Bladder lesion (n=2), bowel serosa lesion (n=2), vaginotomy (n=1); [e] Bladder lesion; [f] Intraabdominal bleeding.

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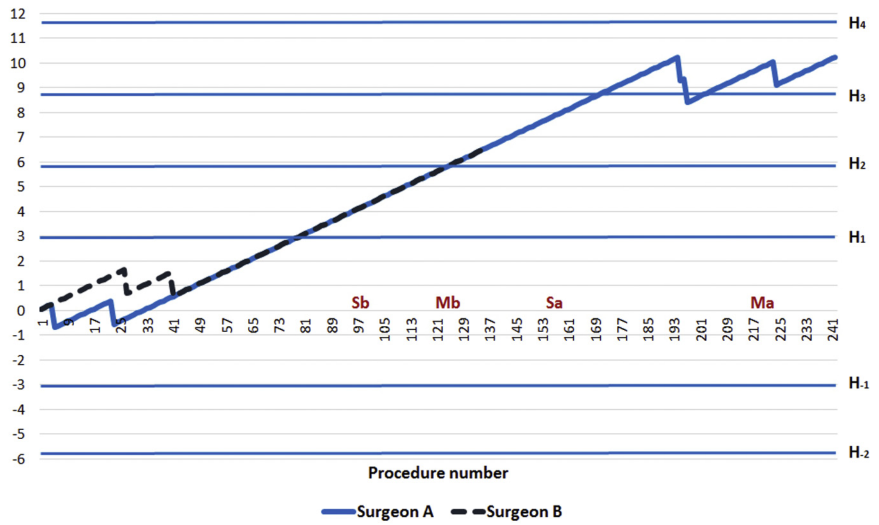
procedures to look for differences in patients' risk profile. Intraoperative complications were defined as any deviation from the ideal intraoperative course between incision and closure, which included conversions as a result of genitourinary, bowel, or vascular injury. Intraoperative complications that were detected postoperatively were scored as well. Because the main objective is surgeon's performance, conversions because of adhesions, anesthetics, or malfunction of the robot were excluded. The Satava Classification system was used to score intraoperative complications.[13]

Time to set up the robot, total time the surgeon was seated in the console to perform the surgery, and total time from first incision until last suture was defined as "robot docking time," "console time," and "total surgery time," respectively. Times were scored separately for RASC and RSCR. The simplified Pelvic Organ Prolapse Quantification[14] examination was used for the determination of stage of prolapse. As result of recent evidence on the prevention of ovarian cancer, in consultation with the patient, a salpingectomy was performed simultaneously at the end of this study.[15] Because of new national and Food and Drug Administration guidelines, in-bag morcellation was performed starting from 2015 to prevent spill in case a sarcoma would be present.[16,17] The start of in-bag morcellation and consequent performance of concomitant salpingectomy is marked in the figures.

This study was judged as an exempt study by the National Central Committee on Research Involving Human subjects. Statistical analysis was performed with SPSS statistics software (version 22.0; IBM, Armonk, NY). Data were presented as number and percentage for categoric data, mean±standard deviation, or median and range for continuous data. The independent *T*-test and 1-way analysis of variance, Mann-Whitney *U* test, and Kruskal Wallis test were used to test shifts in normally distributed and nonnormally distributed continuous values, respectively. Chi squared test and Fisher's Exact test were used for categoric data, as appropriate. Post hoc tests were used in case of significance. All tests were considered significant at .05 level.

FIGURE 1
Cumulative sum control chart analysis of intraoperative complications per surgeon



The *X-axis* indicates the number of procedures performed. The *Y-axis* indicates the cumulative sum of success and failure of the surgeon. The *consecutive line* indicates surgeon A; the *dotted line* indicates surgeon B. Cumulative sum control chart analysis is based on acceptable performance rate of 4.4% and unacceptable performance rate of 8.8%. In case of a complication, the graph falls with 0.936. In case of no complication, the graph rises with 0.064 (Appendix). The *horizontal lines* represent the upper and lower control limits: the boundary lines. Unacceptable perfomace is achieved when the graph falls below H_{-1}. Proficiency is obtained when the graph crosses H_1. The surgeons can cross a second or third boundary line (H_2, H_3), which indicates even better performance. Proficiency can be lost by a fall in the graph and crossing ≥2 boundary lines. The cumulative sum control chart analysis alerts at this point that measurements should be taken to improve performance again. There is an upward slope after 23—41 cases. Proficiency is obtained after 78 cases for both surgeons. For surgeon A, a second trend in complications is seen after 172 complication free cases. The graph never falls in the unacceptable performance zone.

CUSUM, cumulative sum control chart; *Ma*, start of endobag morcellation surgeon A; *Mb*, start of endobag morcellation surgeon B; *Sa*, start consistent salpingectomy surgeon A; *Sb*, start consistent salpingectomy surgeon B.

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TABLE 3
Baseline characteristics and procedures per 25 surgeries

Variable	Age, y[a]	Body mass index, kg/m^2[a]	Parity[b]	Postmenopausal, n (%)	Diabetes mellitus, n (%)	Smoking, n (%)	American Society Of Anesthesiologists grade[b]	History of pelvic organ prolapse/ incontinence surgery, abdominal surgery, mesh surgery, n (%)[c]	Simplified pelvic organ prolapse quantification C[a,d]	Robot-assisted ventral mesh rectopexy, n (%)	Subtotal hysterectomy, n (%)	Concomitant surgery, prolapse, salpingectomy, n (%)
Surgeon A												
0–25	62.8± 9.5	26.2±4.2	2.0 (1–4)	22 (88.0)	1 (4.0)	4 (19.0)	2.0 (1–3)	7 (28.0); 9 (36.0); 1 (4.0)	2.9±1.0	11[e] (44.0)	18[f] (72.0)	6 (24.0); 1 (4.0); 1 (4.0)[g]
25–50	57.0±10.6	25.2 ±2.8	2.0 (1–5)	15 (60.0)	0 (0.0)	7 (29.2)	1.0 (1–3)	12 (48.0); 12 (48.0); 1 (4.0)	2.6±1.0	8[e] (32.0)	15 (60.0)	7 (28.0); 4 (16.0)[g]; 0 (0.0)[g]
50–75	65.0[g]±12.8	25.9± 3.9	3.0 (1–4)	22 (88.0)	2 (8.0)	3 (13.0)	2.0 (1–3)	12 (48.0); 11 (44.0); 0 (0.0)	2.6±1.0	13 (52.0)	14 (56.0)	3 (12.0); 1 (4.0); 0 (0.0)[g]
75–100	65.0[g]±11.1	26.2±2.9	3.0 (0–5)	21 (84.0)	2 (8.0)	4 (16.0)	2.0 (1–3)	8 (32.0); 13 (52.0); 2 (8.0)	3.1±1.0	6[h] (24.0)	18 (72.0)	8 (32.0); 0 (0.0); 2 (8.0)[g]
100–125	57.5±9.3	28.1±4.5	3.0 (1–5)	19 (76.0)	3 (12.0)	5 (20.8)	2.0 (1–3)	13 (52); 13 (52.0); 2 (8.0)	2.5±1.0	13[e] (52.0)	17 (68.0)	7 (28.0); 3 (12.0)[g]; 1 (4.0)[g]
125–150	55.3[g]±11.7	26.3±3.6	3.0 (1–6)	17 (68.0)	1 (4.0)	4 (16.0)	2.0 (1–2)	9 (36.0); 12 (48.0); 1 (4.0)	2.9±1.1	11 (44.0)	17 (68.0)	12 (48.0); 1 (4.0); 9 (36.0)
150–175	61.3±10.6	26.2±4.2	3.0 (2–5)	21 (84.0)	2 (8.0)	5 (20.8)	2.0 (1–2)	16 (64.0); 12 (48.0); 1 (4.0)	2.2±0.9	11[e] (44.0)	11 (44.0)	18 (72.0); 0 (0.0); 18 (72.0)[g]
175–200	57.0±10.5	26.0±3.4	3.0 (0–5)	19 (76.0)	3 (12.0)	6 (26.1)	1.0 (1–3)	8 (32.0); 12 (48.0); 2 (8.0)	2.8±0.9	13[e,i] (52.0)	16 (64.0)	20 (80.0); 0 (0.0); 20 (80.0)[g]
200–225	60.1±11.9	26.8±4.6	2.0 (1–5)	21 (84.0)	1 (4.0)	3 (12.0)	2.0 (1–2)	12 (48.0); 12 (48.0); 4 (16.0)	2.8±0.9	17[e] (68.0)	13 (52.0)	22 (88.0); 0 (0.0); 22 (88.0)[g]
225–end (n=17)	61.1±11.4	26.4±4.0	3.0 (1–6)	13 (76.5)	2 (11.8)	4 (3.5)	2.0 (1–3)	7 (41.2); 11 (64.7); 1 (4.0); 0 (0.0)	2.5±1.1	10[e] (58.8)	9 (52.9)	15 (88.2); 0 (0.0); 15 (88.2)[g]
P value[j]	.011	.481	.980	.227	.777	.906	.110	.251; .923; .655	.110	.123	.584	Not calculated .041 <.0005

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(continued)

TABLE 3

Baseline characteristics and procedures per 25 surgeries *(continued)*

Variable	Age, y[a]	Body mass index, kg/m^2[a]	Parity[b]	Postmenopausal, n (%)	Diabetes mellitus, n (%)	Smoking, n (%)	American Society Of Anesthesiologists grade[b]	History of pelvic organ prolapse/ incontinence surgery, abdominal surgery, mesh surgery, n (%)[c]	Simplified pelvic organ prolapse quantification C[a,d]	Robot-assisted ventral mesh rectopexy, n (%)	Subtotal hysterectomy, n (%)	Concomitant surgery, prolapse, salpingectomy, n (%)
Surgeon B												
0−25	65.5±8.8	25.8±3.7	3.0 (1 −11)	23 (92.0)	4 (16.0)	4 (20.0)	2.0 (1−3)	8 (32.0); 11 (44.0); 0 (0.0)	2.8±1.1	7[g] (28.0)	17[f] (68.0)	9 (36.0); 6 (24.0); 1 (4.0)[g]
25−50	60.7±11.3	26.2±3.1	3.0 (0−6)	20 (80.0)	5 (20.0)	6 (28.6)	2.0 (1−2)	11 (44.0); 11 (44.0); 1 (4.0)	2.4±1.1	10 (40.0)	13 (56.0)	4 (16.0); 1 (4.0); 0 (0.0)[g]
50−75	61.9±13.5	25.5±4.2	3.0 (1−6)	21 (84.0)	1 (4.0)	4 (16.0)	2.0 (1−3)	11 (44.0); 13 (52.0); 0 (0.0)	2.3±0.9	14[i] (56.0)	15 (60.0)	9 (36.0); 6 (24.0); 1 (4.0)[g]
75−100	59.5±9.6	26.9±4.6	2.0 (1−9)	20 (80.0)	2 (8.0)	1 (4.3)	2.0 (1−3)	12 (48.0); 13 (52.0); 1 (4.0)	2.3±1.0	19[g,i] (76.0)	16[f] (64.0)	11 (44.0); 2 (8.0); 10 (40.0)
100−125	58.5±11.5	28.1±4.8	2.0 (1−7)	18 (72.0)	1 (4.0)	5 (21.7)	2.0 (1−2)	11 (44.0); 11 (44.0); 0 (0.0)	2.0±0.8	15 (60.0)	12 (48.0)	16 (64.0); 2 (8.0); 13 (52.0)[g]
125−end (n=12)	60.3±13.0	28.4±4.3	2.5 (0−5)	10 (83.3)	0 (0.0)	3 (25.0)	1.5 (1−2)	6 (50.0); 7 (58.3); 1 (4.0)	2.5±0.9	10[e,g] (83.3)	11[f] (91.7)	11 (91.7); 1 (8.3); 11 (91.7)[g]
P value[j]	.327	.430	.984	.518	.277	.332	.402	.914; .881; .660	.202	.003	.419	not calculated .161 <.0005

[a] Data are given as mean±standard deviation; [b] Data are given as median (range); [c] Other intraabdominal surgery than scored as previous pelvic organ prolapse/incontinence surgery; [d] Value presented as mean±standard deviation because of the limited range of 4; for statistical analysis, Kruskal Wallis test was performed; [e] Includes 1 re-rectopexy; [f] In 1 case, hysteropexy performed instead of subtotal hysterectomy (STH); reasons for hysteropexy were one of following items: very small uterus, severe adhesions, extremely prolapsed tissue; [g] Statistically significant based on post hoc tests; [h] Includes 2 re-rectopexy; [i] Includes 1 resacrocolpopexy; [j] One-way analysis of variance, Kruskal Wallis test, and Pearson's Chi squared test/Fisher's exact test were used to compare mean, median, and nominal variables between groups; post-hoc tests were used in case of significance.

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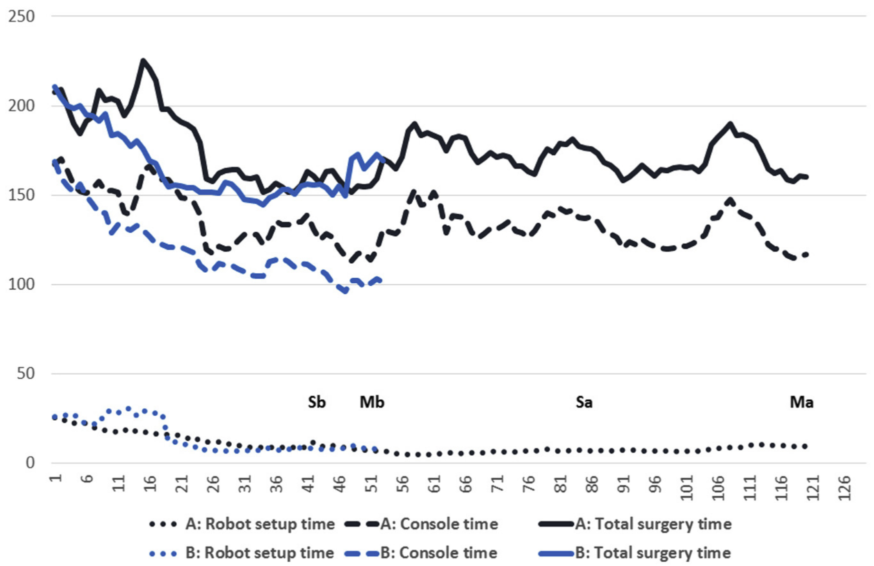
FIGURE 2
Moving average method of surgery time in robot-assisted sacrocolpopexy



Surgery time was ordered, and the mean values were calculated per 10 cases.
The *X-axis* indicates the number of procedures performed. The *Y-axis* indicates surgery time (minutes).

A, surgeon A; *B*, surgeon B; *Ma*, start of endobag morcellation surgeon A; *Mb*, start of endobag morcellation surgeon B; *Sa*, significantly more salpingectomies performed by surgeon A; *Sb*, significantly more salpingectomies performed by surgeon B.

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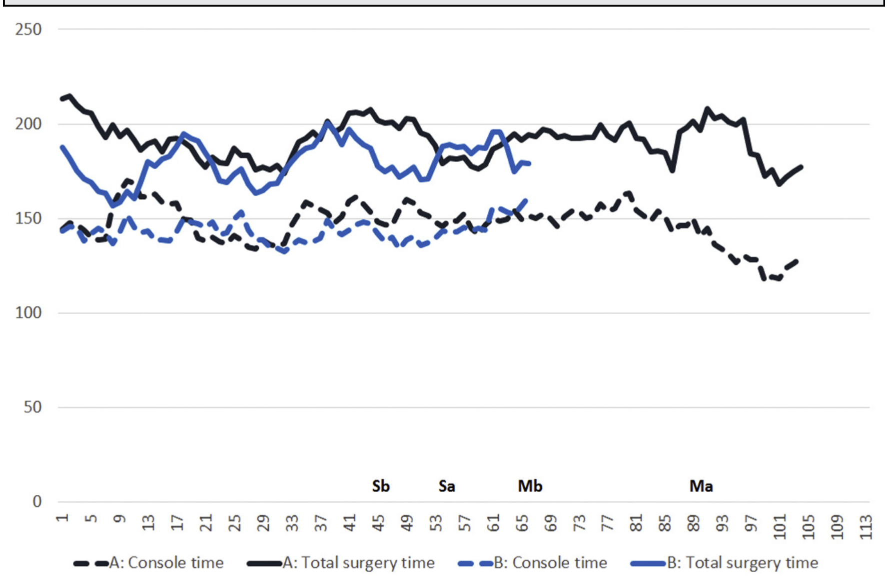
FIGURE 3
Moving average method of surgery time in robot-assisted sacrocolporectopexy



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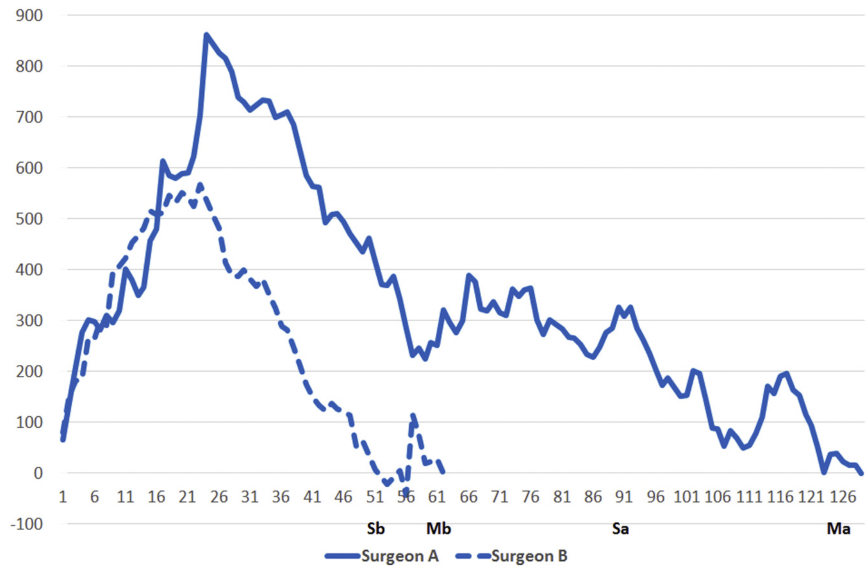
Results

In total 372 surgeries were performed. Surgeon A performed 242 surgeries (RASC, 129 [53.3%]; RSCR, 113 [46.7%]) and Surgeon B 137 surgeries (RASC, 62 [45.3%]; RSCR, 75 [54.7%]). Seven procedures were performed by both surgeons. Baseline characteristics and surgical details are shown in Table 1. Concomitant anterior colporrhaphy was performed more often by surgeon B than by surgeon A.

Intraoperative complications occurred in 1.9% of patients (7/372; Table 2). There were 2 conversions because of adhesions without visceral damage and 2 ventilation-related problems, all of which were not considered to be a complication. There were no conversions because of robotic system failure. Figure 1 shows the CUSUM analysis of the intraoperative complications for both surgeons. Boundary lines were calculated (Appendix). After 2 complications at an early stage, a steadily climbing line was seen for surgeon A after 23 cases and for surgeon B after 41 cases. Proficiency was obtained for both surgeons after 78 cases. A second trend for surgeon A was seen: after 172 complication free cases, new complications arose without falling below 2 unacceptable performance lines. The last 3 complications of surgeon A occurred in case numbers 175—200. Table 3 shows the baseline characteristics per 25 surgeries, forming 10 groups. As a result of the addition of salpingectomy, the number of concomitant surgeries in case numbers 175—200 for surgeon A were significantly different. Furthermore, more RSCRs were performed, with 3 patients receiving re-rectopexy. Looking at all groups of 25 procedures for surgeon A, there was no significant difference in patients' demographics, besides age and concomitant surgery. For surgeon B, there was a significant difference between early and late groups of 25 patients regarding the performance of RSCR and salpingectomy. In-bag morcellation was used starting from procedure number 218 of 242 (RASC, 123/129; RSCR, 96/113) for surgeon A and 126/137 (RASC 60/62; RSCR, 67/75) for

FIGURE 4
Cumulative sum control chart analysis of total surgery time per surgeon in robot-assisted sacrocolpopexy



The *X-axis* indicates the number of procedures performed. The *Y-axis* indicates the cumulative surgery time (minutes). In case the performing time is longer or shorter than mean surgery time, the graph respectively rises or falls with the absolute difference in minutes. Because the rising or falling of the graph is based on mean surgery time, the graph should end on zero minutes again. Surgery time dropped after 20−24 cases.

CUSUM, cumulative sum control chart analysis; *Ma*, start of endobag morcellation surgeon A; *Mb*, start of endobag morcellation surgeon B; *RASC*, robot-assisted sacrocolpopexy; *Sa*, significantly more salpingectomies performed by surgeon A; *Sb*, significantly more salpingectomies performed by surgeon B.

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surgeon B. Describing changes in patients' profile and surgical procedure aids in understanding the CUSUM analysis.

Mean surgery time was 173±39 minutes for RASC (surgeon A, 176±35 minutes; surgeon B, 170±39 minutes) and 187±25.8 for RSCR (surgeon A, 192±40 minutes; surgeon B, 179±36 minutes). Moving averages for surgery time are shown in Figures 2 (RASC) and 3 (RSCR). Robot setup time in RASC stabilized after 29 cases; console time and total surgery time plateaued after 26 cases. Console time and total surgery time corresponded well with each other. In RSCR, no robot setup time was presented because of missing data. Regarding console and total surgery time, no clear pattern was detectable. CUSUM analysis for total surgery time is shown in Figures 4 (RASC) and 5 (RSCR). In RASC, after 24 cases for surgeon A and after 20−23 cases for surgeon B, surgery time started to diminish. Combining results of MOA and CUSUM analysis, a steady state in surgery time was achieved after 24−29 cases for RASC. Again, no clear pattern could be detected for RSCR.

Comment

Principal findings

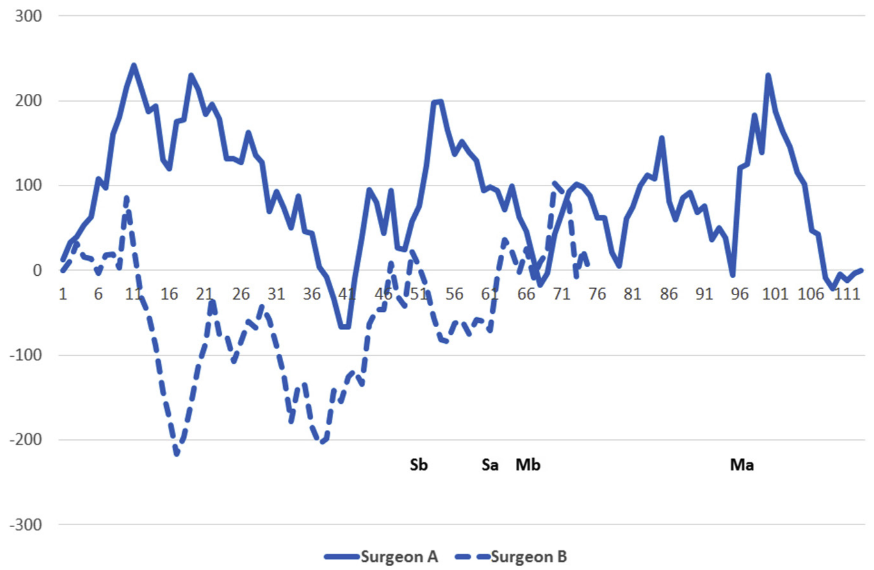
Stabilization of the learning curve regarding intraoperative complications was obtained after 23−41 cases for both surgeons. Proficiency was obtained later, after 78 cases. Intraoperative complications overall were infrequent (1.9%), and neither surgeon performed in the unacceptable zone, which suggests that implementation of RASC/RSCR is safe for experienced laparoscopic surgeons. A second trend in complications was seen after 195 cases for surgeon A. Three new complications occurred, although performance remained acceptable. No difference in patient referral pattern could be detected in this period based on baseline demographics. However, there was a difference in surgical technique at the end of the study. The addition of salpingectomy, performing more multicompartment surgeries, and the start of endobag morcellation could have influenced performance. This should raise awareness that procedures and patient population can change over time. Monitoring results with the aid of CUSUM analysis possibly could signal this and alert surgeons to potential issues.

Stabilization of total surgery time for RASC occurred between 24−29 cases. Regarding RSCR for multicompartment prolapse, there was no clear increase or decrease of surgery time detectable, which suggests that surgeon's experience is not the key factor for diminishing surgery time in this procedure. Other factors, such as team effort, have been shown to diminish surgery times[18] and should be examined possibly to improve efficiency in RSCR. A dedicated robotic team during RASC has been described to decrease operative time by 18%. In RSCR, focus of the team should also be on fluently alternating between surgeons.

Results of the study in the context of other observations

Studies that have reported the learning curve of RASC are scarce, and their methods differ.[19−24] Reduction of mean surgery time of 25% after 10 cases[19] and significant shortening of mean total surgery time after 15 cases (mean surgery time, 187 minutes; n=40) were reported.[20] This quick drop in reduction of total surgery time is comparable with our findings. Linder et al[21] reported that surgery times plateaued after 60 cases. Proficiency was achieved after 55 cases for intraoperative complications and after 84 cases for intraoperative or postoperative complications. Risk-adjusted CUSUM analysis was used, in which complications that occurred in patients with a higher risk profile (based on American Society Of Anesthesiologists classification, body mass index, number of vaginal deliveries) were scored less heavily. Comparing these numbers for proficiency based on intraoperative complications with our results, our

FIGURE 5
Cumulative sum control chart analysis of total surgery time per surgeon in robot-assisted sacrocolporectopexy



The *X-axis* indicates the number of procedures performed. The Y-axis indicates the cumulative surgery time (minutes). In case the performing time longer or shorter than mean surgery time, the graph respectively rises or falls with the absolute difference in minutes. Because rising or falling of the graph is based on mean surgery time, the graph should end on zero minutes again. No clear cutoff point can be estimated.

CUSUM, cumulative sum control chart analysis; *Ma*, start of endobag morcellation surgeon A; *Mb*, start of endobag morcellation surgeon B; *RSCR*, robot-assisted sacrocolporectopexy; *Sa*, significantly more salpingectomies performed by surgeon A; *Sb*, significantly more salpingectomies performed by surgeon B.

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number is slightly higher. Possibly this could be explained by the difference in the applied method of the use of a risk profile. Myers et al[22] performed a CUSUM analysis based on the results of 2 surgeons who performed RASC in a smaller group of patients (surgeon 1, 107; surgeon 2, 62). Both surgeons were performing constantly in the acceptable performance zone, thereby maintaining proficiency the whole time. Their study set the complication target value at 10%, based on previous literature, which is less strict than our target level of 4.4%. Even with our much stricter target level, both surgeons never performed outside of the acceptable performance zone. One systematic review on RASC reports that surgery times drop quickly in the first 10–20 cases based on 2 studies.[24] Complications were scored, but no specific analysis regarding complications and learning curve was made. CUSUM analysis, especially when intraoperative complications are analyzed, can aid surgeons in receiving feedback on their performance and safety. Even small shifts in surgical performance can be detected, which makes this technique very interesting for the rapidly developing industry. Because a limited amount of studies described the learning curve with aid of CUSUM analysis, our results can be an added value to the literature.

Of studies that describe the learning curve of conventional laparoscopy,[25–28] Claerhout et al[25] used CUSUM analysis. The study included 206 patients who chose conventional laparoscopic sacrocolpopexy. Their primary outcome was failure (laparotomy, complications, or anatomic failure <3 months). After 60 cases, the learning curve was obtained (failure <10%). However, failure rate temporarily exceeded the 10% threshold later in the study, which shows that remaining at a 90% success rate is a demanding job.

Looking at the scientific literature and our results, reducing surgery time is very different from accomplishing proficiency. To perform significantly better than the acceptable rate (4.4%) takes much longer than to lower surgery time. The procedure must be performed many times to lower the risk of complications and incidence of injuries.[29] We found surgery time to decrease first, and then the complication rate was lowered. The difference between these types of learning curves should be acknowledged and taken into account when RASC or RSCR is started.

Strengths and limitations

Combining the results of 2 surgeons is a strength of this study. An increase in the CUSUM graph regarding intraoperative complications was seen for surgeon A after 23 cases and for surgeon B after 41 cases. Surgeon B performed fewer surgeries in the same time period. After 2 years, surgeon A had performed 87 surgeries, and surgeon B had performed 49 surgeries. This could have influenced the learning curve because high exposure at regular intervals improves learning. The large number of cases included and the use of the CUSUM technique are other strengths. This study also has its limitations. Two different procedures were included in the CUSUM analysis. This limited the study homogeneity and therefore may have affected the outcome. Another limitation was that concomitant procedures were included in total surgery time. This was corrected partially by the assessment of sheer console time. However, concomitant subtotal hysterectomy remained within console time. Finally, all complications in the CUSUM analysis were of equal weight, whereas there is a difference in the clinical relevance of the different complications.

Clinical implications

With the advent and integration of new techniques, it becomes more important to have a clear understanding of the learning curves of complex surgical interventions. Knowing surgical pitfalls may prepare surgeons better. More important than describing an absolute number of procedures to obtain proficiency, CUSUM analysis can also be used as a tool to individualize training programs. It can alert surgeons when additional training is necessary. Consensus on surgical training is essential, and requirements to begin performing robotic surgery without supervision should be clear.[30] Results from this study indicate that it might be best to perform the first 23−41 cases with an experienced robotic surgeon. Second, an extensive caseload is necessary to obtain proficiency. It should be assessed if this is possible in every hospital. More research in this field therefore is recommended to set up standardized guidelines eventually.

Conclusion

Proficiency based on CUSUM analysis in RSCR was obtained after 78 cases. Stabilization of total surgery time for RASC occurred between 24 and 29 cases. CUSUM analysis could prove to be a useful tool in training programs that are set up for robot-assisted medical devices to determine robotic proficiency. ■

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Appendix

P_0=acceptable failure rate=0.044

P_1=unacceptable failure rate =0.088

Type 1 error (α)=”out of control” false=0.10

Type 2 error (β) ‘in control’ false=0.10

$a=\ln[(1-\alpha)/\beta]=\ln(0.9/0.1)=\ln 9=2.197$

$b=\ln[(1-\alpha)/\beta]=\ln(0.9/0.1)=\ln 9=2.197$

$P=\ln(P_1/P_0)=\ln(0.088/0.044)=\ln 2=0.690$

$Q=\ln[(1-P_0)/(1-P_1)]=\ln[0.956/0.912]=\ln 1.048=0.047$

With ln=natural logarithm $\log_e$.

$s=Q/(P+Q)=0.047/(0.690+0.047)=0.047/0.737=0.064$

Meaning with success, slope goes 0.064 upwards and with failure, slope goes 0.936 (1−s) downwards.

H_{-1} represent the unacceptable boundary lines: $H_{-1}=b/(P+Q)$

H_1 represents the acceptable boundary lines: $H_1=a/(P+Q)$

$H_{-1}=H_1=2.197/(0.690+0.047)=2.197/0.737=2.934$

Notice that because $\alpha=\beta$, this results in $H_{-1}=H_1$ (space between unacceptable and acceptable boundary lines are equal). To determine the extreme boundary lines (H_2, H_3, H_4, etc and H_{-2}, H_{-3}, H_{-4}, etc), the same spacing is used.