Comparison of operative times for robotic-assisted laparoscopic sacrocolpopexy with or without use of StitchKit™

Jennifer L Priestley, PhD
Emeritus Professor of Analytics and Data Science
School of Data Science and Analytics, Kennesaw State University, Kennesaw, Georgia

Patrick J Culligan, MD
Director of Urogynecology, Valley Hospital, Ridgewood, NJ
Disclosure: Dr. Culligan is the inventor of StitchKit™ and is a stockholder in Origami Surgical

ABSTRACT

Objective: To compare operative times for robotic-assisted laparoscopic sacrocolpopexy with or without use of a novel suture & needle management device (StitchKit™, Origami Surgical, Madison NJ).

Methods: This study was conducted as part of an IRB-approved protocol. We carried out a retrospective study of all patients who underwent robotic-assisted laparoscopic sacrocolpopexy (with or without concomitant hysterectomy) at a community hospital between July 2020 and July 2022. Two experienced robotic surgeons ("Surgeon A" and "Surgeon B"), who share the same intraoperative team and utilize identical surgical techniques, performed all surgeries. No residents, fellows or other learners were involved in any of the cases; the only difference between the techniques employed by the two surgeons was that Surgeon A used StitchKit™ and Surgeon B utilized individual sutures passed into and retrieved from the surgical field by the bedside assistant. Both surgeons had performed over 500 robotic assisted laparoscopic sacrocolpopexy cases prior to the study period. Operative times were defined as total anesthesia time recorded in the hospital electronic medical record. Variables thought to potentially influence operative times were recorded and compared using independent t-tests and chi square analyses, as appropriate. These variables were Age, BMI, pelvic organ prolapse quantification (POP-Q) stage, and concomitant sling placement and/or hysterectomy. All analyses were completed using SAS v9.

Results: During the study period, Surgeons A and B performed 193 and 93 robotic-assisted laparoscopic sacrocolpopexy cases, respectively. Baseline patient Age, BMI, and mean POP-Q stage were not statistically different between the two surgeons. Mean operative times (in minutes) for Surgeon A and Surgeon B were 159.8 (±31.9) and 190.9 (±33.9), respectively ($p<0.0001$). Patients treated by Surgeon B were more likely to have had a Sling implant (91.49%, vs 64.25%, $p <.0001$) and may have been slightly more likely to have had performance of concomitant hysterectomy (87.23%, vs 78.24%, $p=.07$). The potential interaction effects of concomitant sling placement, concomitant hysterectomy, and POP-Q stage on the operative times between surgeons were tested using a Generalized Linear Model. There were no interaction effects found for concomitant sling or hysterectomy (p=.84). There was an interaction effect found for POP-Q stage and Surgeon. As POP-Q stage increased from <4 to 4, Surgeon A times increased from 158 minutes to 171 minutes, while Surgeon B times increased from 188 minutes to 281 minutes (p=.0007).

Conclusions: The significant difference between mean operative times by Surgeon A and Surgeon B cannot be explained by experience, surgical technique, surgical team, patient demographics, or any procedural details other than use of StitchKit™. Use of StitchKit™ for suture and needle management during robotic assisted laparoscopic sacrocolpopexy resulted in time savings of greater than 30 min per case.

INTRODUCTION

Pelvic organ prolapse is a common, debilitating problem for which nearly 13% of U.S. women undergo surgical reconstruction [1]. Approximately 300,000 prolapse repair surgeries are performed in the US annually, and this number is expected to increase 50% by 2050 due to the aging U.S. population [2]. The vast majority of prolapse repairs are performed in a minimally invasive route – either vaginally or laparoscopically. A large, ever-increasing, proportion of these laparoscopic surgeries incorporates robotic assistance. When scrutinized via rigorous research methods, traditional "native tissue" prolapse repairs have demonstrated poor objective and subjective success rates [3-5]. However, use of lightweight polypropylene mesh in the form of a robotic sacrocolpopexy results in excellent long-term success rates. The classic approach to sacrocolpopexy utilizes multiple individual sutures fastening a Y-shaped mesh to the vaginal walls making sacrocolpopexy a "suture-intensive" operation. In fact, the aspect of sacrocolpopexy that takes the most time to perform is by far the suturing component. Robotic surgeons typically rely on their surgical assistants who are scrubbed in at the patient bedside to pass sutures into the surgical field and retrieve the used needles. These needle and suture transfers can be inefficient and even dangerous. It is not uncommon for a bedside assistant to drop or otherwise lose a needle inside the surgical field when attempting to remove it through a trocar. The incidence of reported lost or retained instruments following laparoscopic surgery is between 0.06 – 0.11% [6]. However, this range undoubtedly represents a gross underestimate, since it does not reflect cases in which needles are temporarily lost but later safely retrieved. The process of finding a lost needle is very stressful, time consuming, and expensive. In some cases, a lost needle can lead to an otherwise-unnecessary laparotomy for retrieval.

A novel product, StitchKit™ (Origami Surgical, Madison, NJ – Figure 1), is a self-contained suture and needle management system used during robotic surgery. StitchKit™ was designed to enhance safety, autonomy, and efficiency by allowing the surgeon to fully manage suture use and needle disposal within the surgical field while seated at the robotic console. The device, which opens like a clamshell within the surgical field, comes loaded with all of the sutures required to complete the given robotic surgery on one side and a "sharps" container for used needle disposal on the other side.

Beyond simply eliminating the issue of lost needles, use of StitchKit™ is believed to provide efficiencies that can result in significantly shorter operative times. The objective of this study was to determine the differences in operative time for robotic-assisted laparoscopic sacrocolpopexy cases in which StitchKit™ either was or was not used.

METHODS

This IRB-approved study was a retrospective analysis of all patients who underwent robotic-assisted laparoscopic sacrocolpopexy (with or without concomitant hysterectomy) at a community hospital between July 2020 and July 2022. Two experienced robotic surgeons ("Surgeon A" and "Surgeon B"), who work with the same intraoperative team and utilize identical surgical techniques, performed all surgeries. This community hospital is not a teaching institution, therefore none of these cases included residents, fellows, medical students, or other learners. The only difference between the techniques employed by the two surgeons was that Surgeon A used StitchKit™ and Surgeon B utilized the traditional method of individual sutures being passed into and retrieved out of the surgical field by the bedside assistant. Both surgeons had performed over 500 robotic assisted laparoscopic sacrocolpopexy cases prior to the study period. Using the hospital electronic medical record system, we identified all cases of robotic sacrocolpopexy during the two-year study period and compared the resultant list to the surgeons' office case logs for completeness. We defined 'operative time' as total anesthesia time recorded in the hospital electronic medical record. Variables that could potentially influence operative times were compared using independent t-tests and chi-square analyses, as appropriate. Variables considered included patient age, BMI, pelvic organ prolapse quantification (POP-Q) stage [7], and whether concomitant suburethral sling placement and/or hysterectomy were performed. All analyses were performed using a statistical software package (SAS v9., Cary NC).

All surgeries were performed via a previously reported standardized technique [8]. Briefly, supracervical hysterectomies were performed when uteri were present. The vesicovaginal dissections were carried down to the level of the trigone, and the rectovaginal dissections were carried to the level of the perineum (Fig. 2). The polypropylene Y-shaped mesh (Restorelle Y-mesh [Coloplast, Humlebæk, Denmark] was tailored to each patient's anterior and posterior defects and attached to the vagina using interrupted polytetrafluoroethylene sutures (either CV4 Gore-Tex , Gore Medical Products Division, Flagstaff, AZ or PTFE sutures via StitchKit™, Madison NJ), and the same suture material was used to fasten the proximal arms of mesh to anterior longitudinal ligament. The posterior mesh arms were between 9 and 11 cm in length, and the anterior arms were between 5 and 7 cm in length. The mesh was buried beneath peritoneum using zero-gauge poliglecaprone sutures (Monocryl on SH needles; Ethicon, Somerville, NJ). Concomitant mesh midurethral slings were offered to patients who demonstrated preoperative stress incontinence with reduction of their prolapse during urodynamic studies. Other than use of StitchKit™, the two surgeons follow identical surgical steps outlined below and shown in the following full-length, narrated videos:

1) Robotic supracervical hysterectomy and sacrocolpopexy *https://www.youtube.com/watch?v=F1dGujj8LYQ&t=1477s* ;

2) Robotic post-hysterectomy *https://www.youtube.com/watch?v=ecscXcVLV04&t=1072s*

RESULTS

During the study period, Surgeons A and B performed 193 and 93 robotic-assisted laparoscopic sacrocolpopexy cases, respectively. Baseline patient BMI, Age, mean POP-Q stage were statistically similar between the two surgeons (table 1). Mean operative times (in minutes) for Surgeon A and Surgeon B were 159.8 (±31.9) and 190.9 (±33.9), respectively ($p<0.0001$). Patients treated by Surgeon B were more likely to have had a Sling implant (91.49%, vs 64.25%, $p <.0001$). Surgeon B had a slightly higher proportion of cases which included concomitant hysterectomy, although this finding did not reach statistical significance. (87.23%, vs 78.24%, $p=.07$). Surgeon A had a higher proportion of patients with POP-Q Stage 4 (13.5% versus 3.2%, $p=0.001$). The potential interaction effects of concomitant sling placement, concomitant hysterectomy, and POP-Q stage on the operative times between surgeons were tested using a Generalized Linear Model. There were no interaction effects found for concomitant sling or hysterectomy between Surgeons A and B ($p=.84$). There was an interaction effect found for POP-Q stage and Surgeon; as POP-Q stage increased from <4 to 4, Surgeon A times increased from 158 minutes to 171 minutes (17% increase in operative time), while Surgeon B times increased from 188 minutes to 281 minutes (49% increase in operative time) ($p=.0007$).

DISCUSSION

Enhanced surgeon autonomy is often cited as an advantage of robotic surgery over traditional "straight-stick" laparoscopic cases because the robotic surgeon controls the camera as well as all three surgical instruments. During robotic cases, bedside assistants tend to be less critical to the case efficiency, safety and operative time as they are during traditional laparoscopic cases. However, this trend does not hold for "suture-intensive" robotic cases (defined as cases requiring four or more individual sutures / needles), because each needle / suture pass represents an opportunity for inefficiency, needle loss, or even patient injury.

StitchKit™ was designed to enhance surgeon autonomy and efficiency during "suture-intensive" cases while eliminating the risk of needle loss, however no prior studies had confirmed these advantages. This study confirmed operative time savings in StitchKit™ cases that was both statistically and clinically significant.

The fact that Surgeon B had a higher proportion of cases in which concomitant sling was performed did not account for Surgeon B's higher mean operative time. Similarly, Surgeon A's higher proportion of POP-Q Stage 4 cases did not contribute to operative time differences. The biggest difference between POP-Q Stage 4 cases and those cases with < Stage 4 has to do with suturing time. Therefore, the greater proportional difference in operative times for Stage 4 cases between Surgeon A and Surgeon B likely reflected an amplification of the baseline time savings derived from StitchKit™.

Strengths of this study were the uniformity of surgical techniques between surgeons, the fact that both surgeons were well past the surgical learning curve and the fact that they each used the same surgical team.

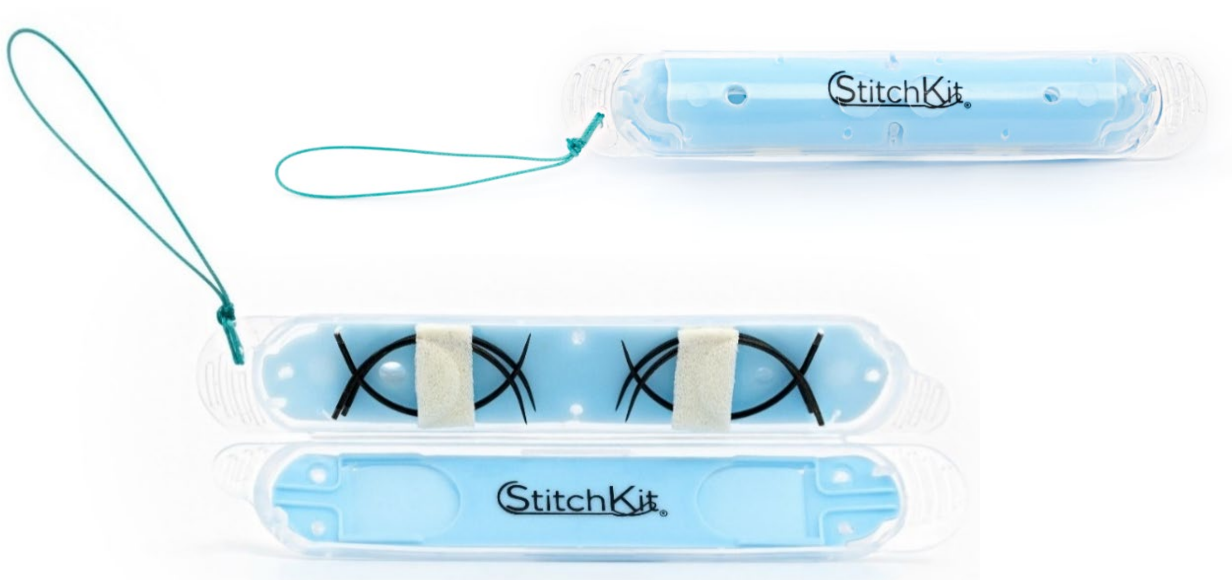
The main weakness of the study was the retrospective design, which conferred the possibility of confounding factors skewing the findings.

Nevertheless, in our series, use of StitchKit™ during robotic-assisted laparoscopic sacrocolpopexy cases was associated with a time savings of greater than 30 minutes per case.

Table 1. Comparison of patient demographics and clinical characteristics.

Characteristic	Surgeon A (N = 193)	Surgeon B (N=93)	p-value
Operative Time (min)	159.8 (±31.9)	190.9 (±33.9)	<0.0001
Age (y)	65.4 (±10)	66.9 (±8.5)	0.45
BMI (kg/m^2)	26 (±4.7)	25.9 (±4.8)	0.87
Prior hysterectomy (%)	21.8	12.8	0.07
Concomitant sling	64.3	91.5	<0.0001
Mean POP-Q Stage	3.08 (±0.43)	3.03 (±0.18)	0.27
POP-Q Stage 1 (%)	0	0	
POP-Q Stage 2 (%)	5.2	0	
POP-Q Stage 3 (%)	81.3	96.8	0.001
POP-Q Stage 4 (%)	13.5	3.2	0.001

Figure 1. StitchKit™ opened and closed



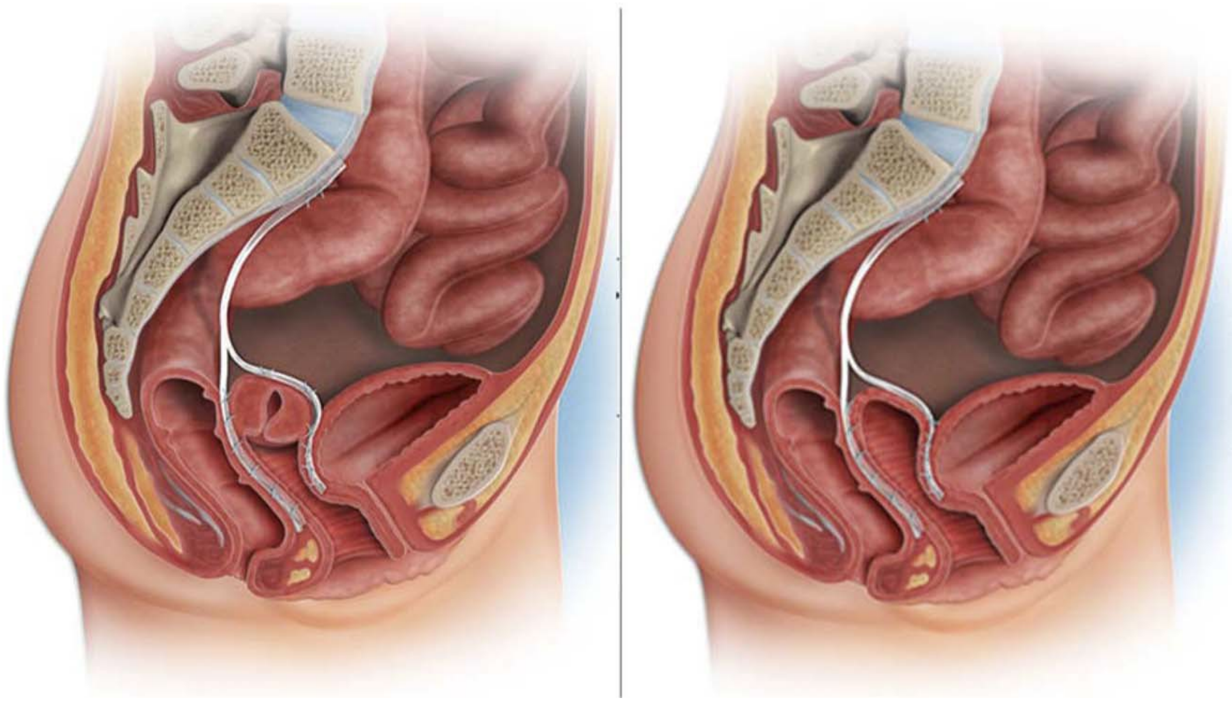


Figure 2. The desired outcomes of robotic assisted laparoscopic sacrocolpopexy with or without concomitant hysterectomy

REFERENCES

1. Wu JM, Matthews CA, Conover MM, Pate V, Jonsson FM. Lifetime risk of stress urinary incontinence or pelvic organ prolapse surgery. Obstet Gynecol 2014;123:1201-6
2. Wu JM, Vaughan CP, Goode PS, et al. Prevalence and trends of symptomatic pelvic floor disorders in US women. Obstet Gynecol. 2014; 123(1):141-148
3. Siddiqui NY, Grime CL, Casiano ER, et al. Mesh sacrocolpopexy compared with native tissue vaginal repair: A systematic review and meta-analysis. Obstet Gynecol. 2015; 125(1):44-55
4. Jelovsek EJ, Barber MD, Brubaker L et al. Effect of uterosacral ligament suspension vs sacrospinous ligament fixation with or without perioperative behavioral therapy for pelvic organ vaginal prolapse on surgical outcomes and prolapse symptoms at 5 years in the OPTIMAL randomized clinical trial. JAMA 2018 ;319(15):1554-1565
5. Nager CW, Visco AG, Richter HE, et al. Effect of sacrospinous hysteropexy with graft vs vaginal hysterectomy with uterosacral ligament suspension on treatment failure in women with uterovaginal prolapse: 5-year results of a randomized clinical trial. Am J Obstet Gynecol 2021; 225(2):153.e1 – 153.e31
6. Jayadevan R, Stensland K, Small A, Hall S, Palese M (2014) A protocol to recover needles lost during minimally invasive surgery. JSLS Soc Laparoendosc Surg 18(4)
7. Bump RC, Mattiasson A, Bø K, Brubaker LP, DeLancey JOL, Klarskov P, Shull BL, Smith ARB. The standardisation of terminology of female pelvic organ prolapse and pelvic floor dysfunction. Am J Obstet Gynecol 1996;175:10–17
8. Culligan, PJ, Saiz, CM, Rosenblatt, PL. Contemporary Use and Techniques of Laparoscopic Sacrocolpopexy With or Without Robotic Assistance for Pelvic Organ Prolapse. Obstetrics & Gynecology 2022;139(5): 922-932