ORIGINAL ARTICLES

Comparison Of Operative Times for Robotic-Assisted Laparoscopic Sacro colpopexy with Or Without Use of a Novel Suture and Needle Management Device

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Objective: *To compare operative times with or without the use of a novel suture and needle management device.*
Methods: *Retrospective study of all patients who underwent robot-assisted laparoscopic sacrocolpopexy during a two-year span. Two experienced robotic surgeons ("Surgeon A" and "Surgeon B") did the cases using standardized techniques except that Surgeon A used a novel suture and needle management device and Surgeon B used individual sutures passed into and retrieved by the bedside assistant. Age, BMI, pelvic organ prolapse quantification (POP-Q) stage, and concomitant sling placement and/or hysterectomy were compared between groups.*
Results: *Surgeons A and B performed 193 and 93 cases, respectively. Demographics were similar between groups. The mean operative times (in minutes) for Surgeons A and B were 159.8 (±31.9) and 190.9 (±33.9), respectively (p<0.0001). Surgeon B's group underwent more slings (91.49% vs. 64.25%, p <.0001) and may have been slightly more likely to have undergone concomitant hysterectomy (87.23% vs. 78.24%, p=.07), but no interaction effects were found (p=.84).*
Conclusions: *The significantly faster mean operative times by Surgeon A cannot be explained by experience, surgical technique, surgical team, patient demographics, or any procedural details other than the use of the novel suture and needle management device.*

BACKGROUND

Nearly 13% of women in the U.S. undergo reconstructive pelvic surgery to correct pelvic organ prolapse, and many more simply choose to live with the problem[1]. In the U.S. alone, over 300,000 such operations are performed annually, and by 2050 this number will be more than 450,000[2]. Most prolapse repairs are performed either vaginally or laparoscopically, with an ever-growing proportion of the laparoscopic cases being done with robotic assistance. Most vaginal prolapse repairs are performed using the "native tissue" approach, but these surgeries have demonstrated poor objective and subjective success rates[3-5]. However, laparoscopic sacrocolpopexy using Y-shaped lightweight polypropylene 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, sacrocolpopexy, which requires the most time to perform, is by far the suturing component. Robotic surgeons typically rely on surgical assistants who are scrubbed at the patient's bedside to pass sutures into the surgical field and retrieve the needles used. Needle and suture transfers can be inefficient and dangerous. It is not uncommon for a bedside assistant to drop or 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

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represents a gross underestimation, since it does not reflect cases in which needles are temporarily lost but later safely retrieved. The process of finding a lost needle is stressful, time-consuming, and expensive. In some cases, a lost needle can lead to unnecessary laparotomy for retrieval.

A novel product, StitchKit™ (Origami Surgical, Madison, NJ,;USA– Figure 1), is a self-contained suture and needle management system used during robotic surgery and 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, is loaded with all the sutures required to complete the given robotic surgery on one side and a "sharps" container for needle disposal on the other side.

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

Figure 1: StitchKit™ opened and closed

MATERIALS AND METHODS

This IRB-approved study (Weill Cornell Medicine IRB protocol number 180801948912001) was a retrospective analysis of all patients who underwent robot-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 worked with the same intraoperative team and used identical surgical techniques, performed all surgeries. This community hospital is not a teaching institution; therefore, none of these cases involved 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 passing individual sutures into and retrieved from the surgical field by the bedside assistant. Both surgeons performed over 500 robotic-assisted laparoscopic sacrocolpopexy procedures 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 with the surgeons' office case logs for completeness. We defined 'operative time' as the total anesthesia time recorded in the hospital's electronic medical record. Variables that could potentially influence operative times were compared using independent t-tests and chi-squared 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 was performed. All analyses were performed using the statistical software package (SAS v9., Cary NC). All surgeries were performed using a previously reported standardized technique [8]. Briefly, for patients with uteri, supracervical hysterectomies were performed. Vesicovaginal dissections were carried down to the level of the trigone, and rectovaginal dissections were performed at the level of the perineum. 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, USA), and the same suture material was used to fasten the proximal arms of the mesh to the 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 peritoneum was covered over the mesh via zero-gauge poliglecaprone sutures (Monocryl SH needles; Ethicon, Somerville, NJ, USA).

Concomitant mesh midurethral slings were offered to patients with demonstrable who preoperative stress incontinence. The only difference in surgical technique between these two surgeons was whether StitchKit™ was used.

RESULTS

During the study period, Surgeons A and B performed 193 and 93 robot-assisted laparoscopic sacrocolpopexy cases, respectively. The baseline patient BMI, Age, and mean POP-Q stage were statistically similar between the two surgeons (Table 1). The mean operative times (in minutes) for Surgeons A and B were 159.8 (±31.9) and 190.9 (±33.9), respectively ($p<0.0001$). Patients treated with 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 that included concomitant hysterectomy, although this finding was not statistically significant. (87.23%, vs 78.24%, $p=.07$). Surgeon A had a higher proportion of patients with POP-Q Stage 4 disease (13.5% vs. 3.2%, $p=0.001$).

The potential interaction effects of concomitant sling placement, concomitant hysterectomy, and POP-Q stage on operative times between surgeons were tested using a Generalized Linear Model. No interaction effects were found for concomitant sling or hysterectomy between Surgeons A and B ($p=.84$).

An interaction effect was found for POP-Q stage and Surgeon; as POP-Q stage increased from <4 to 4, Surgeon A times increased from 158 min to 171 min (17% increase in operative time), while Surgeon B times increased from 188 min to 281 min (49% increase in operative time) ($p=.0007$).

Table 1: Comparison of patient demographics and clinical charicteristics.

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/m2)	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

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. This autonomy can even obviate the role of bedside assistants for certain robotic cases. However, during "suture-intensive" robotic cases (defined as cases requiring four or more individual sutures/needles), skilled bedside assistance is required, as 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 have confirmed these advantages. This study confirmed statistically and clinically significant time savings associated with StitchKit™ use.

The fact that Surgeon B had a higher proportion of cases in which a 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 with < stage 4 has to do with suturing time. Therefore, the greater proportional difference in operative times for stage 4 cases between surgeons A and B likely reflected an amplification of the baseline time savings derived from StitchKit™.

The 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 used the same surgical team.

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

CONCLUSION

In our series, the use of StitchKit™ during robotic-assisted laparoscopic sacrocolpopexy was associated with time savings of greater than 30 min per case.

DECLARATIONS

Funding

There was no funding source for this trial

Author Contributions

Dr. Culligan oversaw collection of the data and wrote the manuscript

Dr. Priestley assisted in writing the manuscript and performed the statistical analyses

Ethical Compliance

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Conflict of Interest

Dr. Culligan is the inventor of StitchKit™ and is a major stockholder in Origami Surgical

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Data available through Dr. Jennifer Priestley jclpriestley@gmail.com

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