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Single-Port Robotic Cholecystectomy

*Results From a First Human Use Clinical Study of the New da Vinci Single-Site Surgical Platform*

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**Objectives:** To report our results from a first human use clinical study with the da Vinci Surgical single-site instrumentation in patients with gallbladder disease and to perform a retrospective comparison with traditional multiport laparoscopic cholecystectomy.

**Design:** Ten patients underwent robotic single-port cholecystectomy performed with the da Vinci Si robot and novel da Vinci single-site instrumentation. Outcomes and operative times were compared with patients undergoing traditional multiport laparoscopic cholecystectomy during the same period.

**Setting:** Tertiary care Veterans Administration hospital.

**Patients:** Outpatients older than 18 years with an American Society of Anesthesiologists class of 1 to 3, no prior upper abdominal surgery, and diagnosis of noninflammatory biliary disease.

**Intervention:** Single-site robotic cholecystectomy.

**Main Outcome Measures:** Operative time, complications up to 30 days, pain scores, and overall satisfaction.

**Results:** Nine of 10 patients had completion of robotic single-site cholecystectomy. Average operating room time was 105.3 minutes compared with an average of 106.1 minutes in the standard laparoscopic group. There were no serious adverse events in the robotic surgery group, with an average follow-up of 3 or more months.

**Conclusion:** Robotic single-port cholecystectomy is feasible and comparable with standard laparoscopic cholecystectomy in the Veterans Administration medical center setting.


**Single-Incision Laparoscopic surgery (SILS) is a recent technical advancement in minimally invasive surgery developed as a less invasive alternative to conventional laparoscopy. According to a recent literature review, a total of 4585 patients underwent SILS in a variety of surgical specialties. The potential advantages of SILS include less pain, quicker recovery, and improved cosmesis. To our knowledge, to date, there has not been a large clinical trial comparing SILS vs standard multiport laparoscopy (MLS), so the clinical benefits of this new technique are purely speculative. What can be deduced from the literature is that there have been significant technical and ergonomic limitations with SILS surgery.

In MLS, the placement of the ports allows for triangulation to the target anatomy, fewer instrument collisions, wide angles of retraction, and better surgeon ergonomic comfort, all of which improve the surgical procedure and its safety. In current SILS, many of these advantages are lost. Instruments enter the abdomen parallel through the umbilicus, resulting in the loss of the triangulation of the target anatomy. In addition, the parallel approach and the resulting lack of space between instruments impair visualization and cause greater collisions between instruments and/or the camera. This may also compromise the ability to retract the target anatomy, resulting in suboptimal tissue exposure. Some surgeons have used transabdominal sutures, magnets, hooks, and other small retraction devices through additional access points to address this issue. However, these solutions are not ideal because the traction obtained is static and unidirectional compared with the dynamic traction in MLS. Some surgeons operate with crossed hands to achieve a typical screen image and comparable hand...
orientation, which can lead to significant mental stress. To minimize these issues, various surgical device manufacturers have developed articulating instruments and flexible endoscopic cameras. These instruments are complex to use, have a learning curve associated with their use, and do not offset all of the ergonomic issues.

In an attempt to address these limitations of manual SILS, surgeons have used the existing da Vinci Surgical System (Intuitive Surgical Inc, Sunnyvale, California) through a single umbilical incision. This application has been reported in 9 articles covering urology, gynecology, and general surgery. Although the application was feasible, it was also associated with limitations because of collisions, especially with crowding of the robotic arms at the single incision.

In a program to optimize SILS with the da Vinci Surgical System, Intuitive Surgical developed a novel set of single-site instruments and accessories. The accessories include a multichannel access port with room for 4 cannulae and an insufflation valve. Two curved cannulae are for robotically controlled instruments. The other 2 cannulae are straight; one is 8.5 mm and accommodates the high-definition and 3-dimensional endoscope and the other is a 5-mm bedside-assistant surgeon port (Figure).

The curved cannulae are integral to the system since their configuration allows the instruments to be positioned to achieve triangulation of the target anatomy. This triangulation is achieved by crossing the curved cannulae midway through the access port. Same-sided hand-eye control of the instruments is maintained through assignment of software of the Si system that enables the surgeon’s right hand to control the screen right instrument even though the instrument is in the left robotic arm and reciprocally the left hand controls the screen left instrument even though the instrument is in the right robotic arm. This coordination of screen images with the operating hand removes many of the current issues of single-port articulated instrumentation, which often is deployed with crossed hands to achieve the same result of screen image and operating-hand coordination.

The second part of the platform is a set of semirigid, nonwristed instruments based with standard da Vinci instrument tips. The semirigid flexible shaft allows for insertion down the curved cannula and triangulation of the anatomy. The bedside-assistant cannula allows for dynamic retraction. In addition, since the surgeon is at the operating console and there is increased space between the robotic arms, there is more than adequate room for the bedside assistant to perform his or her responsibilities. Robotic arm collisions are minimized externally because the curved cannulae angle the robotic arms away from each other. Internal collisions with the camera are avoided because the camera is designed to be placed into the middle of the curved cannula zone and is not in a parallel arrangement as in SILS.

This article summarizes the results of a first human use study of the da Vinci single-site system designed to determine the feasibility and efficacy of robotic single-port laparoscopic cholecystectomy in a Veterans Administration (VA) population and compares these results with traditional MLS in the same patient population.

**METHODS**

**INVESTIGATIONAL SUBJECTS**

Patients older than 18 years were recruited from the outpatient surgical clinic at the Palo Alto Veterans Hospital. Inclusion criteria included patients with the radiographic diagnosis of biliary colic, gallbladder polyps less than 7 mm, biliary dyskinesia, or a history of gallstone pancreatitis or acute cholecystitis. Exclusion criteria were American Society of Anesthe-
tery hook, and suction irrigator) were then used to perform a monopolar cautery, monopolar curved scissors, Hem-O-Lok clip applier (Weck Closure Systems, Research Triangle Park, NC), and laparoscopic grasper. The robotic arms were swapped such that the screen right instrument was being controlled by the right master and vice versa.

Fundibulum. At the console, the surgeon confirmed that the right colon was clear of the gallbladder before proceeding with the dissection of the gallbladder bed. The assistant surgeon grasped the dome of the gallbladder with a bariatric length grasper (to increase distance from the robotic instruments). The 8.5-mm camera trocar and camera were inserted first through the midpoint of the umbilicus. The fascia was made through the midpoint of the umbilicus. The fascia was made with an interrupted suture and the skin, with a subcuticular closure. Patients were transported to the recovery unit and then the short-stay ward.

DATA COLLECTION VARIABLES

Patient demographics, including sex, age, preoperative diagnosis, intraoperative diagnosis, pathologic diagnosis, and American Society of Anesthesiologists class, were collected. Procedure-specific variables of total operative, docking, console, incision, and closure times were recorded. Patients were assessed postoperatively for any adverse event out to 30 days. Visual analog scale pain scores were obtained at discharge and in the postoperative clinic.

INSTITUTIONAL REVIEW BOARD

The study was conducted under the approval and monitoring of the Stanford University institutional review board and Palo Alto Veterans Administration Health Care System Research Committee.

RESULTS

A total of 10 cases were performed with the single-site platform. All patients had a preoperative diagnosis of biliary colic. Surgery was able to be completed in 9 of 10 patients (90%). Patient demographics were typical of a VA population, with 7 of the 10 patients being male and 6 of 10 found to have intraoperative evidence of inflammatory disease including significant omental adhesions or gallbladder inflammation. Two of 10 patients had an intraoperative diagnosis of gallbladder empyema with hydrodrops. Final pathologic diagnosis was chronic cholecystitis in all patients and was not a helpful variable. The single operative conversion was in a patient who had significant adhesions of the omentum to the diaphragm, in addition to severe cholecystitis with a shrunken gallbladder. This patient was excluded from the total operative time and outcome data analysis because of the conversion first to MLS cholecystectomy and then to open cholecystectomy. The average age of the experimental group was mean (SD) 58.8 (15.9) years (range, 33-83 years) and the average body mass index (BMI) (calculated as weight in kilograms divided by height in meters squared) was mean (SD) 27.7 (3.3) (range, 25.5-34.6). A control group of 10 sequential outpatients undergoing MLS cholecystectomy was used for comparison. Seven of 10 were male and 4 of 10 had an intraoperative diagnosis of significant inflammation and 1 patient each had hydrodrops and severe cholecystitis. The average age and BMI of the control group was not significantly different than the experimental group: mean (SD) age, 61.8 (15.6) years (range, 26-86 years) (P = .70); mean (SD) BMI, 28.4 (6.2) (range, 23.2-39.3) (P = .76).

Table 1 summarizes the comparison between the investigational and control groups.

Table 1. Control vs Investigational Group Summary

<table>
<thead>
<tr>
<th></th>
<th>Control: Laparoscopic Cholecystectomy</th>
<th>Robotic Single-Site Cholecystectomy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total No. of patients</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Inflammatory disease, %</td>
<td>40</td>
<td>60</td>
</tr>
<tr>
<td>Conversions, No. (%)</td>
<td>0</td>
<td>1 (10)</td>
</tr>
<tr>
<td>Major complications, No. (%)</td>
<td>1 (10)</td>
<td>0</td>
</tr>
<tr>
<td>Operating time, min, mean (range)</td>
<td>106.1 (70-142)</td>
<td>105.3 (82-139)</td>
</tr>
</tbody>
</table>

Control: Multiport Laparoscopic Cholecystectomy

Institutional Review Board

The study was conducted under the approval and monitoring of the Stanford University institutional review board and Palo Alto Veterans Administration Health Care System Research Committee.

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OPERATIVE TIME

In the investigational group, only the 9 patients whose operation was successfully completed without conversion were included in analysis. The mean (SD) total operative time was 105.3 (18.32) minutes (range, 82-139 minutes). The mean (SD) operative time in the control group was 106.1 (23.53) minutes (range, 70-142 minutes). There was no significant difference in operative times between the 2 groups (\(P = .93\)). Within the investigational cohort, there did not appear to be a significant learning curve for the procedure based on total operative times. The 3 cases without any inflammation had a mean operating room (OR) time of 85 minutes (range, 82-88 minutes), and the 2 patients with empyema and hydrops had times of 139 and 120 minutes. The difference in OR times appeared to be primarily related to the degree of inflammation present, not case number performed.

Robotic single-port operative times were further analyzed based on operative task and are summarized in Table 2. The 4 times are (1) skin incision through curved cannula insertion under camera visualization, (2) docking of the 2 robotic arms and camera port, (3) surgeon time at the console performing a full cholecystectomy including bagging the specimen, and (4) time from port and specimen withdrawal through fascial and skin closures. The skin incision time had a single outlier case of 32 minutes. In this case, the instruments had not completed their sterilization cycle so there was a delay after incision. If this case was censored, the average time from skin incision to cannula insertion would have been mean (SD) 14.9 (4.7) minutes. Operative console time ranged from 38 minutes at its briefest in a 33-year-old woman with no inflammation to 99 minutes in a 46-year-old woman with severe inflammation and gallbladder hydrodrops and empyema. During the series, the technique of closing the fascia changed from a running suture to interrupted sutures because the latter were easier to perform with the small incision.

PATIENT OUTCOMES

Outcomes were measured only in the 9 patients who underwent a successful robotic approach. All patients were discharged the morning after surgery. The visual analog scale score (range, 1-10) summary demonstrated a mean (SD) score of 2.5 (1.4) (range, 0-4) at the time of discharge and a mean (SD) score of 0.67 (0.87) (range, 0-2) at the postoperative clinic visit 2 to 3 weeks after surgery. Two male patients had urinary retention and required at least 1 episode of catheterization in the first postoperative night. A single patient was discharged with a urinary catheter, which was successfully removed the week after surgery. There were no late complications that developed in the 30-day postoperative period, and no new complications related to the surgery were reported in a mean follow-up of 201 days (range, 151-291 days). There were no cases of intraoperative complication. There were 2 cases of device malfunction when a small piece of the access port device tore off during placement of the extraction bag and had to be retrieved. Specimen bag-insertion technique was subsequently changed to preserve port integrity, with no further incidence in the remaining cases. All patients reported a high degree of satisfaction with the surgery on follow-up telephone call at 30 days and would recommend the surgery to a friend or family member. In the control group, there were 2 cases of urinary retention in male patients and 1 case of postoperative atrial fibrillation.

Interest in SILS has been growing. Reports of SILS prostatectomy, hysterectomy, colectomy, cholecystectomy, and other solid-organ surgery have been published. The most commonly reported procedure has been SILS cholecystectomy. Antoniou et al recently published a literature review of single-incision cholecystectomy. Their inclusion criteria consisted of English or German studies with greater than 10 subjects, the surgery had to be completed without additional port placements, and results must include conversion and complications. They analyzed a total of 29 articles detailing results on 1166 patients. They found a conversion rate of 9.3%, mean operative time of 70 minutes (range, 30-150 minutes), intraoperative complication rate of 2.7% (range, 0%-32.4%), postoperative complication rate of 3.4% (0%-20.1%), and mean length of stay of 1.4 days (range, 0-4). Our results compare favorably with these results. Our VA first human use study yielded a conversion rate of 10% and an overall minor complication rate of 20%, all urinary retention, for the robotic single-site group. We had no major intraoperative or late-term complications even with extended follow-up greater than 6 months. In contrast, the Antoniou et al summary reported postoperative complications that would be classified as serious, including bile leak, bleeding, infection, residual common duct stone, and biliary sticture. The operative time range reported by Antoniou et al overlaps that seen in the current study, but the mean OR time was higher in the VA study patients. This difference is most likely due to differences in patient population. Antoniou et al found that studies that included patients with a BMI more than 30 and acute cholecystitis and a higher percentage of male patients (>30%) had longer operative times. The VA robotic single-site patient cohort included a majority of patients with acute disease and who were male, which most likely accounts for the longer operative time. There was no difference in mean OR times when the investigational cohort was compared with the last 10 sequential VA patients undergoing traditional laparoscopic cholecystectomy. We speculate that this represents the type of patient typically seen in the VA.

### Table 2. Robotic Cholecystectomy Task Time Breakdown

<table>
<thead>
<tr>
<th>Task</th>
<th>Average Time, min, Mean (SD) [Range]</th>
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<tbody>
<tr>
<td>Skin incision to cannula insertion</td>
<td>16.6 (7) [8-32]</td>
</tr>
<tr>
<td>Docking of robotic arms</td>
<td>4.5 (2.7) [3-12]</td>
</tr>
<tr>
<td>Operative console</td>
<td>63.2 (19.7) [38-99]</td>
</tr>
<tr>
<td>Port removal and closure</td>
<td>18 (3.6) [12-22]</td>
</tr>
</tbody>
</table>

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medical center compared with the typical outpatient in a community setting. Veterans Administration patients are clearly more likely to be male, a factor associated with worse gallbladder disease, than the prototypical female patient who presents with symptomatic gallbladder problems.

In the cohort, there did not appear to be a learning curve associated with the da Vinci single-site robotic platform when comparing operative times within the group. This would have to be rigorously investigated in a larger trial but our first impression is that the operative time is most affected by the degree of gallbladder inflammation. It is the practice of one of us (S.M.W.) to do an open Hasson technique in MLS cholecystectomy so there is some similarity to the single-port entrance and closure but the single-port incision is 2 to 2.5 times larger and therefore may take more time to close compared with a Hasson port. The benefits of SILS are as yet undetermined. Potential benefits include decreased pain, improved cosmesis, shorter recovery, and higher patient satisfaction. These potential benefits over standard cholecystectomy still need investigation. In the meantime, there are significant limitations associated with manual SILS, including visualization, triangulation of target anatomy, and ergonomics. The da Vinci single-site instruments and accessories enabled single-incision surgery and helped minimize the limitations associated with a manual approach. The curved cannulae allow the robotic arms to spread out, minimizing collisions and enabling instrument triangulation with coordination of instrument handedness and screen view. The presence of a bedside-assistant port enables dynamic traction to facilitate safe dissection. The 3-dimensional endoscope controlled by the surgeon provides exquisite visualization and eliminates collisions either with the bedside surgeon or intra-abdominal instruments, which is a distinct advantage over existing manual SILS. The high-definition camera provides an excellent view during dissection and the critical view was easily achieved even with significant inflammation. There is better ergonomic comfort for the surgeon when seated at the console. If indicated, a cholangiogram can be performed by placing a catheter into the cystic duct through a subcostal angiocatheter and then fluoroscopy can be performed after the robot is undocked. One possible limitation of this study is not having a control group of manual SILS cholecystectomies to compare the data. Only 5 manual SILS have been performed in our VA hospital because of the type of gallbladder disease typically present in our patients and the wish to find “easy” cases on which to start SILS. Only 2 of these cases have been able to be completed without the addition of another retraction port and had operative times of 70 and 100 minutes. Chow et al. recently compared outcomes of 41 patients (29% male) who underwent SILS with 58 patients operated on via the standard MLS approach. This cohort of single-port surgeons represented the start of their SILS experience and therefore is comparable with our investigational group of robotic single-port surgeons. The inclusion and exclusion criteria were similar to our data set. Their single-incision data also compared results with a retrospective sample of their standard MLS surgeries. In their group of 41 single-incision patients, 8 (19.5%) had either insertion of additional ports or conversion to standard MLS cholecystectomy owing to the inability to adequately expose the Calot triangle. The mean (SD) operative time for the SILS was 126 (42.9) minutes. Overall, our robotic cohort showed less OR time variation, fewer conversions, and shorter total operative times.

In conclusion, the da Vinci single-site platform performed equivalently to traditional multiport cholecystectomy in this human use study. This study offers distinct advantages over currently available single-port instrumentation and techniques and reestablishes some of the basic principles of laparoscopic surgery, namely triangulation of instruments, dynamic retraction, and camera placement centered on the target anatomy. This approach appears to be safe, even in difficult cases with inflammation, and has a high degree of satisfaction with the patients. This study was done to prove feasibility and efficacy of the new operative platform and additional trials would need to be performed to directly compare it with current single-port surgery.

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Author Contributions: Dr Wren had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Wren and Curet. Acquisition of data: Wren and Curet. Analysis and interpretation of data: Wren and Curet. Drafting of the manuscript: Wren and Curet. Critical revision of the manuscript for important intellectual content: Wren and Curet. Statistical analysis: Wren. Administrative, technical, and material support: Wren and Curet.

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REFERENCES

Are We Making Progress?

Robotic Single-Incision Laparoscopic Surgery

The article by Wren and Curet demonstrates nicely that robotic technology can be enhanced and adapted to changes in surgical technique. Single-incision laparoscopic surgery has been quite the hot topic in the past several years and has been shown to be effective in accomplishing even intricate surgical procedures. Clearly, there is a learning curve for the method and compromises in traditional technique have been made to permit tissue manipulation. These adjustments are often unnatural to the surgeon and require practice to master. The addition of a modified robot to the procedure certainly seems to ameliorate the learning curve and facilitate the performance of the procedure in uncomplicated cases. It is also certain that with continued use, modifications and improvements in the robot and technique would permit the performance of more difficult cases and maneuvers.

While one can argue that the use of single-incision laparoscopic surgery may not seem warranted or necessary, when looked at in the light of progress, one can easily imagine that the robot will eventually add significant value in the performance of complex hepatobiliary surgery. The maturation of single-incision laparoscopic surgery is an important stage in the evolution of minimally invasive surgery, and Wren and Curet are to be commended for their diligent efforts to advance this field.

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