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# Postoperative Pain After Single-Site Versus Multiport Hysterectomy

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### ABSTRACT

**Background and Objectives:** With advances in laparoscopic surgery, the goal of surgeons and patients is to minimize pain to allow for faster recovery and return to normal daily activities. One of these advances is single-site surgery. In this study, we compared postoperative pain in laparoendoscopic single-site surgery (LESS) to that in traditional multiple-incision hysterectomy.

**Methods:** Seventy patients were selected for this prospective cohort study, with 35 undergoing multiple-incision and 35 undergoing LESS hysterectomy. All patients were included who were undergoing hysterectomy with the primary surgeon. All multiport hysterectomies were performed laparoscopically. Six patients underwent LESS hysterectomy and 29 underwent robotic single-site surgery (rLESS). Patients recorded pain levels for 3 weeks after surgery on a variety of measures, including overall and incisional pain. Linear mixed effects models for repeated measures were used for all multivariate analyses, with an unstructured covariance matrix accounting for correlation between time points.

**Results:** Overall, across all time points, there was an average reduction in pain by 1.26 (SD 0.69) points in the single-site group (P = .06). Days 3 and 14 had a marginally significant reduction in pain (P = .06 and 0.058, respectively). On days 4 and 7 there was a significant reduction in overall pain (P = .04 and .04, respectively).

**Conclusion:** Based on the results, it is likely that singlesite hysterectomy leads to less postoperative pain and achieves a lower pain score faster than multiport surgery.

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A randomized control trial is necessary to confirm these results before accepting them in clinical practice.

Key Words: hysterectomy, pain, single-incision

### **INTRODUCTION**

Laparoendoscopic single-site (LESS) is gaining popularity in the field of gynecology and is a desirable skill for most advanced laparoscopic surgeons, as identified by the increasing literature on the subject.<sup>1,2</sup> Surgeons with advanced laparoscopic training start closer to proficiency and have a much faster learning curve with LESS surgery.<sup>3</sup> Thus far, there has been limited and conflicting research in the effectiveness of LESS and its outcomes in gynecologic surgery.<sup>2</sup> The technique was first introduced in the 1970s, when gynecologic surgeons began performing surgery through the umbilicus. Wheeless<sup>4,5</sup> first performed tubal ligations at this time, using an offset eyepiece and a bipolar device to electrocoagulate the fallopian tubes. Because the incision is hidden inside the umbilicus, it is considered "scarless surgery." Although these physicians and procedures were gaining recognition as pioneering in laparoscopy, the surgeries were challenging and had limited use. Over the years, laparoscopy has moved forward with advancing technology. The 1980s saw numerous laparoscopic surgery firsts, including an appendectomy in 1983, a cholecystectomy in 1985, and a hysterectomy in 1989.<sup>6,7</sup> The first laparoscopic hysterectomy using a single incision was reported by Pelosi only a couple of years later in 1991.8 The technique did not become widely popular at that time, likely because of the difficult learning curve and lack of effective instrumentation. It was not until general surgery began publishing success with appendectomies and cholecystectomies in the mid-2000s that LESS regained use in gynecologic surgery.8

Gynecologists across the country are performing more laparoscopic and robotic surgeries because of the benefits of minimally invasive surgery.<sup>8</sup> The advantages of these less invasive surgeries are well documented, no matter what the surgical method. They include the ability to visualize the entire abdomen to safely perform the surgery and examine

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surrounding structures, improved recovery times with shorter hospital stays, and decreased morbidity and pain.<sup>3,9</sup> With these improvements, patients are undergoing hysterectomies in surgical centers and as same-day surgery. To maximize the benefits of minimally invasive surgery, gynecologists are continuously trying to reduce the invasiveness of our procedures, while maintaining beneficial outcomes.<sup>10,11</sup> A few gynecologic studies have shown some initial postoperative benefit from pain reduction with LESS.<sup>10–13</sup> Other single-incision studies have been feasibility studies and had limited evaluation of patients' recovery or pain.<sup>14</sup>

Despite a lack of definitive evidence favoring LESS in gynecology, recent general surgery literature has shown the benefits of LESS for patients undergoing cholecystectomy and a variety of other procedures.<sup>3</sup> A recent metaanalysis of cholecystectomies showed an improvement in cosmesis and postoperative pain with LESS.<sup>15</sup> Other general surgery studies have resulted in similar conclusions, but little research has been performed for hysterectomy.<sup>16,17</sup> For this study, we hypothesized that patients undergoing LESS hysterectomy recover faster with less pain throughout the recovery process than patients who undergo multiple-port hysterectomy.

# **METHODS**

This study is a prospective cohort study looking at pain after laparoscopic hysterectomy as the primary outcome and multiple secondary outcomes, including medication usage, cosmetic benefit, blood loss, uterine size, and surgical time. All surgeries were performed by a fellowshiptrained specialist in minimally invasive gynecologic surgery at Baylor College of Medicine. The study was performed with Institutional Review Board (IRB) approval from Baylor College of Medicine (Houston, TX), along with IRB approval from CHI Baylor St. Lukes (Houston, TX). Baylor IRB approval was accepted for research purposes at Ben Taub Hospital and Texas Children's Hospital. Based on previous literature, we determined that to achieve 80% power in detecting a 1-point differential in reported pain scores, with  $\alpha = .05$ , a sample of 60 subjects would be required. Seventy patients were enrolled to adjust for a predicted 85% response rate for the postoperative survey. Patients were consecutively enrolled immediately after IRB approval was obtained, until 35 patients were enrolled in each group. There were no exclusion criteria for enrollment. In each group, patients were enrolled sequentially, with no randomization.

#### **Multiport Hysterectomy Group**

The multiport hysterectomy group was selected from patients at Ben Taub Hospital, a public institution, and 1 patient from Texas Children's Hospital who were scheduled for surgery for nonmalignant indications. Only multiport hysterectomy was performed at Ben Taub because of the lack of a robot console at this location. At this location, resident participation and teaching were incorporated into the surgeries. The single case at Texas Children's Hospital was a combined surgery with a provider who desired multiport laparoscopy. All patients underwent multiport hysterectomy using three 5-mm abdominal incisions, 1 in or above the umbilicus, with 2 additional ports in the lower left and right quadrants. A supraumbilical incision was used in the case of prior vertical midline surgical scars that extended to the umbilicus. No local injection was used at any port site. The procedure was performed with ultrasound energy and a bipolar system. All specimens were extracted vaginally, with all vaginal cuffs closed with barbed, delayed absorbable sutures.

#### **LESS Group**

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The second group involved patients who were undergoing hysterectomy for benign indications at St. Luke's Hospital or The Women's Pavilion at Texas Children's Hospital under the same specialist in minimally invasive gynecologic surgery. Initially, the study was designed to randomize these patients to the single- or multiple-incision group, but because these patients were referred to the surgeon specifically for single-incision surgery, this approach was not feasible. Thus, patients were not randomized, and the next best possible study design, a prospective cohort, was chosen. In this group, a robot was available for all surgeries, and there was a fellow in minimally invasive gynecologic surgery involved with every case, as well as the occasional resident. Conventional LESS was performed for uteri too large to allow access to superolateral anatomic structures with the robotic (r)LESS port, which generally was for uteri greater than 20 wk in size. A 2- to 3-cm umbilical incision was created at the base of the umbilicus and a 3-cm fascial incision was made. No local injection was used at the port site. Either an Intuitive Surgical (Sunnyvale, California, USA) singlesite port or a Gelpoint (Applied Medical, Rancho Santa Margarita, California, USA) was placed in the incision. A fenestrated bipolar device and monopolar hook were used for ligation and dissection. If LESS was performed, ultrasonic energy and a bipolar device were used. In both the rLESS and LESS groups, the procedures were performed with similar surgical steps and methods. The umbilical port site was then closed with delayed absorbable or permanent (if patient had an umbilical hernia) suture, with the knots buried. In all cases in both groups, if the uterus was too large to deliver intact vaginally, it was placed in a bag and extracted manually through either the vagina or umbilicus. All vaginal cuffs were closed with a barbed, delayed absorbable suture.

#### Patient Outcomes and Follow-up

Patients in both groups were discharged within 24 h of surgery, with a prescription for acetaminophen-codeine, ibuprofen, and docusate, unless there was a contraindication. All patients were then seen for a follow-up visit at 3 to 6 weeks.

All study participants were asked to complete a form that recorded postoperative pain on days 0, 1, 2, 3, 4, 7, 14, and 21. They were asked to record their overall pain, pain specific to their incision site or sites, pain from constipation, or shoulder pain. A 10-point verbal rating scale was used to record the patient's pain level on each day for every pain category. A rating of 0 was described as "no pain," a rating of 5 was described as a "moderate pain-as with an abdominal workout," and a rating of 9 was described as pain "severe-like being stabbed with a knife." Patients were also asked to monitor the number and type of pain medications used each of those days. After 3 weeks, an additional 10-point verbal rating scale was used to have patients rate the appearance of the incision 3 weeks after surgery. In this scale, a 0 was "looks terrible" and 9 was "looks better than before."

Last, we analyzed surgical time, blood loss, quality and number amount of adhesions, number of prior uterine surgeries, and uterine weight. Surgical time was reported in minutes. Blood loss was reported in milliliters. The quality and number of adhesions were described as no adhesions, minimal adhesions (requiring less than 5 minutes of lysis of adhesions), moderate adhesions (requiring 5–30 min for lysis and not including enterolysis), or dense adhesions (greater than 30 min of lysis or enterolysis). Prior uterine surgery was defined as the sum of the number of cesarean deliveries and myomectomies. Uterine weight was then recorded from pathology records in grams.

## Statistical Approach

Standard univariate statistics were used to describe the patient population and assess pain outcome scores throughout the study period. Means and standard deviations were used to describe continuous variables, and frequencies and percentages were used to describe categorical variables. Student's t test and Fisher's exact test were used to compare demographic and clinical characteristics between groups, as appropriate. Linear mixed-effects models for repeated measures were used for all multivariate analyses, with an unstructured covariance matrix accounting for correlation between time points. All models were assessed for potential group interactions with time. When significant, results are reported at the level of the interaction; otherwise, main effects are reported. SAS, ver. 9.4 (SAS Institutes, Cary, North Carolina, USA), was used for all analyses, and marginal significance was defined as P = .05-.1.

# RESULTS

Seventy patients provided consent to participate in this study. Thirty-five patients underwent multiport hysterectomy. and 35 underwent single-incision hysterectomy. Of the 35 who underwent single-incision laparoscopy surgery (SILS), 29 (83%) had rLESS, and 6 (17%) had conventional LESS. Twenty-six of 35 (74%) patients completed the postoperative survey in the multiport group, and 25 of 35 (71%) completed the survey in the LESS group.

Demographic characteristics by hysterectomy group are provided in **Table 1**. No significant difference in age, estimated blood loss (EBL), surgical time, or uterine size was detected between the groups. A significant difference was detected in the body mass index (BMI), race, the number of prior cesarean deliveries, and adhesions (P < .001, P < .001, and P = .05. respectively).

Figure 1 shows box plots of the mean BMI, uterine weight, estimated blood loss, and total operating time for the 2 groups. The average length of surgery was 137 (SD 36) minutes for the multiport group and 152 (SD 81) minutes for the LESS group, with no difference detected between the groups (P = .31). The average uterine weight was similar between groups: 266 (±188) g for the multiport group and 254 ( $\pm$ 320) g for the LESS group (P = .85). There is a marginal difference between the groups (P = .062) in regard to estimated blood loss with  $120 (\pm 139)$  mL for the multiport group and 70 ( $\pm$ 74) mL for the LESS group. No difference in indication for surgery was detected between the groups (P =.28). In the multiport group 74% was for abnormal uterine bleeding, 5.7% was for complex hyperplasia, 11% was for leiomyoma, and 8.5% was for pelvic pain. In the LESS group, 63% was for abnormal uterine bleeding, 17% was for leiomyoma, and 20% was for pelvic pain.

**Figure 2** shows the trend of the average pain score for the 2 study groups. On average, multiport hysterectomy scored 1.26 (SD 0.69) points higher on the overall pain scale across all time points (P = .07). For both groups,

Table 1.   Demographic Characteristics of Multiport and LESS Hysterectomy Groups				
Variables	Multiport (n = $35$ ) Mean (SD) or n (%)	Single Incision (n = $35$ ) Mean (SD) or n (%)	<i>P</i> *	
				Mean age (SD)
Mean BMI (SD)	38.46 (9.48)	29.07 (7.02)	< 0.00	
Mean surgery time (min)	136.94 (35.93)	152.30 (81.43)	0.31	
Mean estimated blood loss (mL)	120.0 (138.9)	69.51 (73.75)	0.06	
Mean uterine size (g)	265.91 (187.80)	253.60 (320.08)	0.85	
Race, n (%)				
African-American	7 (20)	7 (20)	< 0.00	
Hispanic	23 (66)	2 (6)		
White	5 (14)	22 (63)		
Asian	0	4 (11)		
Prior cesarean delivery, n (%)				
0	8 (23)	26 (74)	< 0.00	
1	4 (11)	1 (3)		
2	11 (31)	3 (9)		
3	11 (31)	3 (9)		
4	1 (3)	2 (6)		
Adhesions, n (%)				
None	9 (26)	20 (57)	0.05	
Minimal	11 (31)	8 (23)		
Moderate	5 (14)	3 (9)		
Dense	10 (29)	4 (11)		

\*Two-sample *t* test used for continuous variables and Fisher's exact test for categorical variables. Bold indicates statistically significant results.

the overall pain decreased significantly over time (P <.001) and the rate of decline was marginally faster in the LESS group (P = .08). No difference in pain was detected immediately after surgery (P = .42), on day 1 (P = .49), or on day 2 (P = .15). On day 3, patients in the LESS group reported a 26% decrease in pain score, compared with the multiport group, a marginally significant result (P = .06). On day 4, a 34% decreased pain score was reported (P = .04) in the LESS group, as well as a 48% decreased pain score on day 7 (P = .04). By day 14, average pain was rated 52% lower (P = .058) in the LESS group, but no difference was detected between groups at day 21 (P = .14). When pain scores were compared among the participants in the LESS and rLESS groups, no difference was detected (Table 2.) These results are exploratory, because there were only 6 patients in the laparoscopic group.

**Figure 3** shows the results for incisional pain from surgery. On average, the multiport group scored 0.39 (SD 0.41) points higher on the pain scale across all time points compared to the LESS group; however, this difference is not statistically significant (P = .35). The overall pain decreased significantly over time (P < .001), but the rate of decline did not differ between groups.

Similar results were reported for medication use after surgery. Patients in the LESS group reported less use of Tylenol 3 (Janssen Pharmaceutica, Inc., Titusville, NJ, USA) over the recovery time (P = .06), with a marginally significant difference on day 14 (P = .054). Use of Motrin (Johnson & Johnson, New Brunswick, NJ, USA) showed a marginal decrease in the LESS group per day over time (P = .08).

There was a slight decline in constipation pain (P = .04) over time in both groups; however, no significant difference was

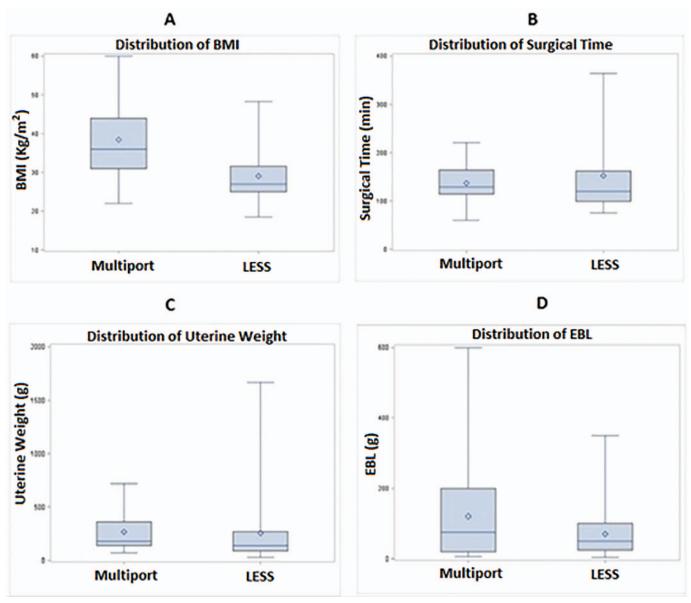
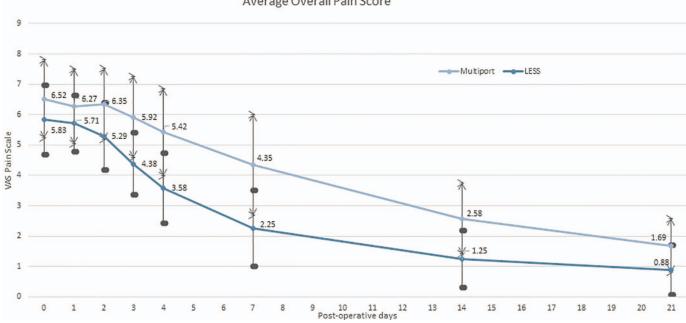


Figure 1. Box plots comparing distributions of (A) BMI, (B) operating time, (C) uterine weight, and (D) estimated blood loss.

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found between groups (P = .20). A significant difference in shoulder pain between groups was detected over time (P = .003). On days 0 and 1, the multiport group had lower rater shoulder pain than the LESS group (P = .004 and P = .001, respectively). By day 2, the difference was only marginally significant (P = .07), and there was no significant difference in shoulder pain scores between the 2 groups after 2 days. There was also no significant difference in cosmesis, with average scores of 8.33 (SD 1.17) for the LESS group and 7.77 (2.21) for the multiport (P = .26).

There were no intraoperative complications in any of the surgeries, either multiport or LESS. There was 1 conversion to multiport robotic surgery by urology during a combined case of lithotripsy after attempted rLESS. A postoperative pelvic abscess developed in 1 patient in the LESS group  $\sim 8$  weeks after surgery. One patient in the multiport group had a cuff abscess detected on postoperative day 10. Both abscesses required minimally invasive drainage. As of 6 months to 1 year after the surgeries, no umbilical hernias have been identified.



#### Average Overall Pain Score

Figure 2. Overall pain scores with 95% CI.

Table 2.LESS versus rLESS Subgroup Analysis				
Outcome	Mean Difference*	95% CI	Р	
Overall pain	1.72	-0.45 to +3.89	0.11	
Incision pain	0.53	-1.56 to +2.63	0.60	
Constipation	0.10	-1.01 to $+1.21$	0.85	
Shoulder pain	0.53	-1.21 to $+2.27$	0.54	
Tylenol usage	0.77	-0.47 to $+2.01$	0.21	
Motrin usage	0.70	-0.33 to +1.73	0.17	

\*Mean difference in pain score for rLESS compared to LESS across all time points and average difference in amount of medication used across all time points.

# DISCUSSION

SILS is gaining popularity throughout the world. It is used increasingly by advanced gynecologic surgeons, especially as surgical skills and instrumentation improve.<sup>2</sup> Previous literature has described clinical significance in the cosmetic value of the surgery and early reduction of pain after surgery.<sup>18,19</sup> A recent publication has shown the feasibility of single-incision surgery in gynecologic oncology cases, and current studies are under way to show the feasibility in all gynecologic surgery.<sup>20</sup> As mentioned previously, research in general surgery has shown the advantages of LESS surgery, including reduction in pain.15-17 By using a single umbilical incision, we

are using an "embryologic natural orifice " into the abdominal cavity and minimizing abdominal wall trauma.<sup>21</sup> This also eliminates the risk of any entry or lateral vessel or nerve injury. Our study adds to the current general surgery literature and expands the benefits of LESS to gynecology by suggesting a decrease in pain during recovery after LESS hysterectomy.

In this study, LESS patients reported a decreased level of overall postoperative pain throughout the recovery process, with an overall average pain score that was lower by 1.26 points (P = .07), with marginal statistical significance. The overall pain reported by LESS patients on days 4 and 7 showed a significant reduction of pain (34%, P = .04, and 49%, P = .04), respectively. By week 2, patients were nearly pain free in both surgical categories, but even then, SILS showed a 53% reduced pain score reported with marginal significance (P = .058). These results suggest that patients have less pain overall and return to baseline faster with LESS than with multiport hysterectomy. There is no difference between the overall recovery rate for both surgeries over the 3 weeks and both rates of improvement are statistically significant, but LESS patients had generally less pain overall. Although, a randomized control trial is necessary to confirm these results. Figure 2 shows the distinct trend for lower reported pain in the LESS group. With statistically significant or marginally significant decreased pain scores on postoperative day 3, 4, 7, and 14 compared to multiport hysterectomy, LESS patients may

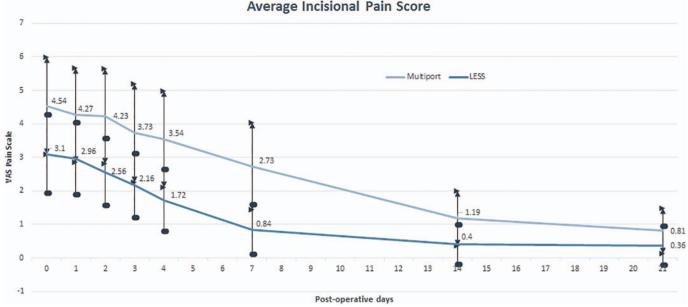


Figure 3. Incision pain scores with 95% CI.

return to normal activities sooner and with reduced pain, which is the ultimate goal with any minimally invasive surgery. Prior studies have shown immediate improvement in pain after surgery, although our study did not show a difference in the first 2 days after surgery.<sup>18</sup> The faster recovery correlates with our clinical observations, as most patients report little to no pain after single incision surgery and have experienced a very rapid, full recovery.

The reported incisional pain showed a significant decrease in both groups over time (Figure 3), but the difference between the 2 groups was not significant (P = .35). In laparoscopic surgery, we expect incisional pain to be well tolerated at baseline, and prior studies have shown increased incisional pain from larger incisions resulting in overnight hospital stays.<sup>22</sup> Based on our data, we cannot confirm that removing the lateral incisions with SILS results in decreased incisional pain. Although Figure 2 appears to show decreased pain with SILS, the results did not achieve statistical significance. The lack of a significant difference may be attributable to the single, larger incision, or the reason may be simply that the study was underpowered to evaluate incisional pain specifically. Also, there was a significant difference between the groups in adhesive disease, with the multiport group having more dense adhesions. This condition may affect the overall general pain reported by patients. Further research would be necessary to identify the exact nature of the source of the patient's pain and to evaluate incisional pain.

We did not see any differences between constipation or throat pain between the groups. There was an increase in shoulder pain on postoperative days 0 and 1 in the singleincision group. This outcome was contrary to what would be expected, as with a single incision, the gas should be completely released from the abdomen through the 2.5-cm incision, as one would see in open surgery. It is possible this pain was a result of a steep Trendelenburg position or retained pockets of gas, whereas in laparoscopic surgery, a point is made to express all the gas from the abdomen at the conclusion of the surgery.

Based on our literature review, this is the first prospective study to look at pain after single-site hysterectomy past the immediate postoperative time. Strengths of the study are that all surgeries were performed by a single specialist in minimally invasive gynecologic surgery and no patients were excluded from enrollment. We looked at multiple sources of pain to search for confounding factors, which helped verify the reduction in reported overall pain. Our goal from a preliminary power analysis was to analyze 60 pain scores, which would have been an 85% response rate with our patient sample size. We were able to analyze only 51 (73% response rate) of the enrolled patients' pain scores. Although, even with a 73% response rate, we achieved significant results. There is also potential for a response bias, with patients experiencing more pain being more likely to respond.

One limitation of this study was the demographic differences between the 2 groups, a previously noted selection bias, owing to the lack of randomization. At Ben Taub, where all the multiport surgeries were performed, with the exception of 1 patient, participants were noted to have larger BMIs, to have had increased cesarean deliveries, and to be a largely Hispanic population. This hospital center also lacked robotic surgery capability. For this reason, future studies with randomization are necessary to verify these results.

When comparing LESS and rLESS, there was no difference between the groups. However, the total number of laparoscopic SILS cases was small, which made detection of differences difficult. Overall, our study suggested a benefit of LESS in the field of gynecology, which should encourage future research in single-incision surgery.

From the data obtained, combined with our clinical experience, we feel our results coincide with prior general surgery results that LESS surgery leads to less postoperative pain and faster recovery than multiport laparoscopy. Although LESS may have a steeper learning curve and require more advanced training, it is a skill acquirable by many experienced laparoscopists. Once acquired, it could be a valuable surgical method used to increased cosmetic benefit, while reducing postoperative pain and speeding up recovery for all patients.

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