

# Vaginal Cuff Closure during Robotic-Assisted Total Laparoscopic Hysterectomy: Comparing Vicryl to Barbed Sutures

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## ABSTRACT

**Background and Objectives:** Empirical evidence is needed to assess clinical appropriateness of any new surgical device or material. Differences in surgical outcomes between Vicryl figure-of-8 and V-Loc barbed sutures for vaginal cuff closure during robotic hysterectomy were assessed.

**Methods:** We examined the electronic medical records of 202 patients who underwent scheduled robotic-assisted total laparoscopic hysterectomy for benign indications, without concomitant urogynecologic procedures, between January 2008 and November 2010 at the Henry Ford Health System academic medical center. Cuff closure approach was selected by the surgeon. Data on demographics, vaginal cuff suture type, body mass index (BMI), estimated blood loss (EBL), perioperative hemoglobin change, procedure duration, hospital length of stay (LOS), specimen weight, and postoperative complications were obtained.

**Results:** The average age was 46 y (SD = 8.0 y). Women with Vicryl figure-of-8 closures (n = 133) were more likely than women with V-Loc barbed suture closures (n = 69) to have had a LOS > 1 d (48/133, 36.1% vs. 12/69, 17.4%; chi square  $P = .006$ ), greater EBL (median 75 vs. 50 mL, Wilcoxon Rank Sum=WRS  $P < .001$ ), and longer procedure durations (175 vs. 135 min, WRS  $P < .001$ ). These differences persisted even after considering uterine weight, BMI, smoking status, and concomitant oophorectomy. No differences with respect to the frequency of major (2 in each closure type) or minor complications were observed ( $P = .36$ ).

**Conclusions:** There were no differences in complications between the Vicryl figure-of-8 and V-Loc barbed sutures

in our sample. However, the latter had lower EBL and shorter procedure duration and LOS.

**Key Words:** Vaginal cuff closure, Hysterectomy.

## INTRODUCTION

The American Association of Gynecologic Laparoscopists (AAGL) recommends that “most hysterectomies for benign disease should be performed either vaginally or laparoscopically.”<sup>1</sup> Although minimally invasive routes have been shown to require shorter hospital stays, faster return to normal activities, and reduced morbidity,<sup>2</sup> most benign hysterectomies in the United States are still performed through a laparotomy.<sup>3</sup> Developments in surgical techniques and equipment *may* reverse this trend over time. Recently, it was proposed that new suture material—specifically, unidirectional barbed sutures—would have a “most profound impact” on laparoscopic procedures by helping to overcome previously difficult-to-perform closure techniques.<sup>4</sup>

As with the introduction of any new medical device or technology, empirical evidence is needed to assess clinical appropriateness of the new device or, in this case, material and approach. Data have been needed to evaluate the use of these barbed sutures in clinical practice compared with materials that have been considered “usual” in clinical care. In this retrospective study of women who underwent robotic-assisted laparoscopic hysterectomy for benign conditions at our academic hospital, we compared the immediate and short-term (at least 5 mo) surgical outcomes of women who had vaginal cuff suturing with Vicryl (polyglactin 910) figure-of-8 sutures with the outcomes of women who had V-Loc 180 polyglyconate unidirectional barbed sutures. We also compared major and minor complication rates between the 2 suture approaches.

## MATERIALS AND METHODS

After institutional review board approval was obtained, a query of Current Procedural Terminology (CPT) codes was run using the Henry Ford Health System medical

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claims database to identify all patients who underwent hysterectomy after gynecologic robotic hysterectomy was initiated at Henry Ford in January 2008. The women's electronic medical records (EMRs) were then reviewed for this retrospective cohort study. We include in this analysis patients who underwent scheduled robotic-assisted total laparoscopic hysterectomy between January 1, 2008, and November 19, 2010. Patients who had had a supracervical hysterectomy, cancer surgery, or a concomitant urogynecological procedure, such as vaginal repair, urethral suspension, or sacrocolpopexy, were excluded, because these types of procedures have differing intraoperative and postoperative considerations.

All surgeries were performed by a cadre of 6 gynecologic surgeons and 2 American Association of Gynecologic Laparoscopists (AAGL) Minimally Invasive Surgery fellows. Standardized techniques for patient positioning, uterine manipulator placement, entry to the peritoneal cavity, size and location of trocar placements, and surgical procedure were used by all surgeons. All procedures were performed using either the standard da Vinci 3-armed platform or the da Vinci-S or Si 4-armed robotic platform (Intuitive Surgical, Sunnyvale, CA) at Henry Ford Hospital Main or Henry Ford Hospital West Bloomfield. The barbed suture closure was performed using V-Loc 180 unidirectional polyglyconate monofilament, (Covidien, Mansfield, MA), and the figure-of-8 closure was performed using a Vicryl braided polyglactin 910 suture, (Ethicon, Inc, Somerville, NJ).

The colpotomy was performed using da Vinci monopolar shears with a pure cutting current. The vaginal cuff was closed horizontally regardless of suture type used, and care was taken to perform full-thickness closures incorporating the vaginal epithelium and the pubocervical fascial ring in each bite. In cases using barbed sutures, a 2-layer closure was achieved by anchoring one suture at each angle and overlapping the suture lines in the midline; the sutures were then stitched back toward their angles of origination to complete a second layer. The uterosacral ligaments were incorporated into the cuff closure to provide apical support. In cases using Vicryl suture, angles were fixated with figure-of-8 sutures that incorporated the full thickness of the vaginal wall as well as the uterosacral ligaments. Additional figure-of-8 sutures were placed as deemed appropriate to completely close the cuff, between 4 and 6 in total for most cases. Hemostasis was obtained using monopolar coagulation when necessary, taking care not to devitalize tissue by using excessive electrocautery.

All data were collected from the EMR. Height, weight, estimated blood loss (EBL in mL), and procedure duration (in minutes) were obtained from the operating room and anesthesia records. Procedure duration was defined as the time between the start of the procedure ("cut") and finish ("close") in the operating room record, which also included the initial placement of the uterine manipulator. EBL was obtained from both the anesthesia records and the surgeons' operative reports. EBL was a consensus estimate by the anesthesiologist and the surgeon using the difference between the total amount of fluid irrigated and aspirated. Uterine weight (in grams) was obtained from the pathology reports. Oophorectomy (unilateral or bilateral), immediate complications, transfusion information, and hospital length of stay (LOS) were all obtained from a review of the EMR, which includes the operative report, discharge summary, and all outpatient clinical and hospital records and telephone contacts. BMI was calculated by dividing the patient's weight in kilograms by the square of their height in meters ( $\text{kg}/\text{m}^2$ ). Smoking status also was collected from the EMR.

Details of all complications were collected from the EMR. These included postoperative vaginal spotting, formation of granulation tissue, bleeding, vaginal cuff dehiscence, pelvic collection or abscess, and the need for further office or operating room treatment. Complications were categorized as major or minor on the basis of whether they required further treatment or hospitalization. grade 1 or 2 complications based on the Clavien-Dindo Classification of Surgical Complications were considered minor, and grade 3 complications were considered major.<sup>5</sup> The postoperative data were collected for a minimum of 5 mo from the date of surgery for each woman.

Data were described using medians and ranges. Wilcoxon rank sum tests were used to compare the continuous values of age, BMI, pathology weight, EBL, procedure duration, and LOS between the closure groups. Fisher's exact tests were used to compare the dichotomous outcomes (readmission, major complication, minor complication, any major or minor complication) between the groups. Linear regression models (procedure duration, log transformed EBL) and logistic regression models (LOS more than 1 d, any major complication, any minor complication) were used to assess whether oophorectomy, pathology weight, current smoking status (yes or no), or BMI confounded (altered) the relationships between the closure type and the outcomes. A P-value  $\leq 0.05$  was considered statistically significant.

Because the V-Loc barbed suture was a newly introduced material, we repeated our analyses for only the 50 most-recent cases in each group to remove potential bias that might occur as a result of the learning curve for the use of a new product. Two V-Loc procedures were completed on 1 of the days; therefore, 51 of the V-Loc cases were examined.

**RESULTS**

Vaginal cuff closures were made with V-Loc barbed sutures in 69 (34.2%) of the women patients and with Vicryl figure-of-8 sutures in 133 (65.8%) of the women patients. Oophorectomy (unilateral/partial or bilateral) at the time of surgery was completed at similar rates for women with Vicryl figure-of-8 sutures (42/133, 31.6%) and women with V-Loc barbed sutures (28/69, 40.6%) ( $\chi^2 P = .20$ ). The groups did not differ with respect to age, BMI, or pathology weight (**Table 1**). The rates of smoking dif-

fered between the 2 groups (27.8% of women with Vicryl figure-of-8 sutures vs. 13.0% of women with V-Loc barbed sutures;  $\chi^2 P = .02$ ).

Women with the Vicryl figure-of-8 closure were more likely to have had an LOS > 1 d, compared with women with the V-Loc closure (48/133, 36.1% vs. 12/69, 17.4%;  $\chi^2 P = .006$ ). Women who had the Vicryl figure-of-8 closure tended to have greater blood loss and longer procedure durations than did women with the V-Loc closure (**Table 1**). Nine (4.5%) readmissions occurred: 2 women (2.9%) in the V-Loc group (both for pelvic collection and fever) and 7 women (5.3%) in the Vicryl figure-of-8 group (vaginal cuff dehiscence, 2 with pelvic abscess, 2 with pelvic hematoma/collection, 1 vesicovaginal fistula, 1 vaginal bleeding excision of granulation tissue) (Fisher's exact  $P = .72$ ). Major or minor complications occurred in 23 women (11.4%): 6 (8.7%) in the V-Loc group and 17 (12.8%) in the Vicryl figure-of-8 group ( $\chi^2 P = .39$ ).

Eleven (5.5%) major complications occurred: 3 (4.4%) among women with the V-Loc suture (2 pelvic collections, 1 vaginal bleeding that required figure-of-8 suture in the emergency department) and 8 (6.0%) among women with the Vicryl figure-of-8 closures (vesicovaginal fistula, excision of granulation tissue for bleeding, 2 pelvic collections, 3 pelvic abscesses, 1 vaginal cuff dehiscence) (Fisher's exact  $P = .75$ ). Twelve (5.9%) minor complications occurred: 3 (4.4%) among women with the V-Loc closure (2 granulation tissue, vaginal bleeding that resolved spontaneously) and 9 (6.8%) among women with the Vicryl figure-of-8 closure (3 vaginal bleeding, 4 spotting, 2 cuff granulation) (Fisher's exact  $P = .75$ ).

Linear regression models (log-transformed EBL, procedure duration) and logistic regression models (procedure duration, LOS > 1 d, any major complication, any minor complication) were used to assess whether oophorectomy, pathology weight, current smoking status, or BMI confounded the associations between closure type and the outcomes. On the basis of a change in effect criteria of at least 20%, the following variables did not confound the associations between closure type and each outcome (excluding procedure duration): any oophorectomy, weight of the specimen, current smoking status, or BMI. Again, in the models, EBL was lower in the V-Loc group, for which the geometric mean was 58.6% (95% confidence limit [CL] 46.5%, 74.5%) of the geometric mean of the Vicryl figure-of-8 group. Procedure duration was weakly confounded by uterine weight. After adjusting for uterine weight, procedure duration was about 36.5 min less (95% CL -54.8, -18.2 min) in the V-Loc group. The odds of having an LOS

**Table 1.**

Patient Information and Immediate Surgical Outcomes by Suture Type

	n	Median	Range	P Value <sup>a</sup>
Age	202	45	29 to 87	.89
Vicryl Figure-of-8 Suture	133	45	30 to 67	
V-Loc Suture	69	45	29 to 87	
Body Mass Index (kg/m <sup>2</sup> )	202	30.7	14.8 to 56.9	.16
Vicryl Figure-of-8 Suture	133	30.3	14.8 to 56.2	
V-Loc Suture	69	32.7	18.0 to 56.9	
Pathology Weight (g)	199	170	52 to 1290	.98
Vicryl Figure-of-8 Suture	130	160	53.6 to 1290	
V-Loc Suture	69	190	52 to 770	
Estimated Blood Loss (mL)	202	50	10 to 1000	<.001
Vicryl Figure-of-8 Suture	133	75	10 to 1000	
V-Loc Suture	69	50	10 to 300	
Procedure Duration (min)	200	160	30 to 625	<.001
Vicryl Figure-of-8 Suture	133	175	80 to 625	
V-Loc Suture	67	135	30 to 299	
Length of Stay	202	1	1 to 14	.01
Vicryl Figure-of-8 Suture	133	1	1 to 14	
V-Loc Suture	69	1	1 to 9	

<sup>a</sup>P value for comparison of Vicryl figure-of-8 sutures with V-Loc barbed sutures based on a Wilcoxon Rank Sum test.

that was more than 1 night was also decreased in the V-Loc group (odds ratio = 0.37, 95% CL 0.18, 0.76). We repeated all analyses after limiting the V-Loc group to the 51 most recent (all procedures after 6/10/2010), and the Vicryl figure-of-8 group to the 50 most recent (all procedures after 12/22/2009). The descriptive information about this subgroup appears in **Table 2**. The results of the analyses were similar to those for the entire cohort; however, the difference in LOS did not remain statistically significant (**Table 2**).

**DISCUSSION**

No difference in complication rates was observed between the Vicryl figure-of-8 group and the V-Loc group; however, the V-Loc group had better outcomes in LOS, EBL, and procedure duration. Our results indicate that women who had vaginal cuff closures with V-Loc barbed sutures tended to have less blood loss and shorter procedure times and LOS compared with women who had vaginal cuff closures with Vicryl figure-of-8 sutures. Oo-

phorectomy, BMI, smoking status, and uterine weight could not explain the observed differences. Complication rates were low for both groups, and no statistically significant differences were found in our retrospective cohort. Differences in complication rates may exist and might have been too small to detect with our sample size. We have provided confidence limits to facilitate assessment of the precision of our estimates. Future prospective studies should determine sample sizes that will allow the data to detect clinically meaningful differences. In addition, a cost analysis taking into consideration the cost of the sutures, the operating room time costs, and costs of further treatment due to complications might also provide insight in the evaluation of new materials.

In the context of clinical practice, interpretation of our findings is not straightforward. A shorter procedure duration using the running barbed sutures versus multiple interrupted figure-of-8 sutures is reasonable given the surgical techniques that are required to complete the closure. The difference in blood loss is more difficult to explain, because the vaginal cuff does not typically bleed profusely, so although the time for completion of vaginal cuff closure is longer with the figure-of-8 suture, it should not considerably affect the total amount of blood loss. This is actually reflected in the analyses, because while the difference in EBL between the suture groups is statistically significant, the medians only differ by 25 mL. Similarly, we believe that the longer hospital length of stay with the Vicryl figure-of-8 vaginal cuff closure may not be clinically meaningful: both groups had median LOS of 1 d for the full cohort and the difference did not remain statistically significant in the subgroup analyses of the most recent cases.

Our results on immediate surgical outcomes were similar to a case series of total laparoscopic patients.<sup>6</sup> In another study comparing incidence of vaginal cuff dehiscence after laparoscopic closure, Siedhoff et al.<sup>7</sup> reported a lower rate among women who underwent bidirectional barbed suturing (n = 149 surgeries) compared with all other closure methods (n = 238 surgeries, 9 with monofilament suture and 229 with braided sutures) (0.0% vs. 4.2%; P = .008). We had only 1 cuff dehiscence (with the Vicryl figure-of-8 closure) in the entire cohort. Interestingly, Siedhoff et al. reported more cuff dehiscence for robotic (n = 54) vs. conventional laparoscopic (n = 333) procedures (7.4% vs. 1.8%, P = .04). They reported no differences in EBL or specimen weights between the groups. Further comparisons between our cohort and that of Siedhoff et al. are complicated, as our procedures were performed with a robotic assist, our comparison group

**Table 2.**

Patient Information and Immediate Surgical Outcomes By Suture Type for the 51 Most Recent V-Loc Barbed Suture Procedures (All After 6/10/2010), and the 50 Most Recent Vicryl Figure-of-8 Procedures (All After 12/22/2009)

	n	Median	Range	P Value <sup>a</sup>
Age				.05
Vicryl Figure-of-8 Suture	50	47	31 to 64	
V-Loc Suture	51	44	29 to 66	
Body Mass Index (kg/m <sup>2</sup> )				.15
Vicryl Figure-of-8 Suture	50	29.7	18.6 to 51.6	
V-Loc Suture	51	31.1	18.0 to 56.9	
Pathology Weight (g)				
Vicryl Figure-of-8 Suture	49	200	53.6 to 1290	.87
V-Loc Suture	51	220	55 to 770	
Estimated Blood Loss (mL)				.08
Vicryl Figure-of-8 Suture	50	50	20 to 1000	
V-Loc Sutures	51	50	10 to 300	
Procedure Duration (min)				.005
Vicryl Figure-of-8 Suture	50	183	80 to 625	
V-Loc Suture	49	135	30 to 299	
Length of Stay				.17
Vicryl Figure-of-8 Suture	50	1	1 to 5	
V-Loc Suture	51	1	1 to 9	

<sup>a</sup>P value for comparison of Vicryl figure-of-8 sutures to V-Loc barbed sutures based on a Wilcoxon Rank Sum test.

comprised a single closure type, and we examined all complications. Unlike Siedhoff et al. we did not include cases in which only trachelectomy was performed.

Our study was a retrospective cohort study that included women from a single surgical group. Although randomized control trials (RCTs) are often considered the gold standard in deciding optimal clinical care protocols, nonrandomized epidemiological studies such as ours provide excellent evidence and should gain greater influence in clinical practice. As surgeons seek more cost-effective and time-effective minimally invasive surgical approaches, new techniques and technology will constantly emerge. With time and economical limitations, RCTs will not be feasible for every new technique or technology. As more women seek minimally invasive treatments and robotic assist allows more surgeons to provide the recommended minimally invasive treatment options, empirical data are needed to evaluate the best approaches for performing the minimally invasive procedures. Whereas our data included women who had a minimum of 5 mo of follow-up data, long-term outcomes for each closure type should be assessed and compared to identify best surgical practices.

In summary, we think that shorter operating time and the absence of an increase in complication rates compared with the more commonly used interrupted figure-of-8 suture technique makes the V-Loc vaginal cuff closure a sound clinical alternative that should undergo long-term investigation.

## **CONCLUSION**

There were no differences in complication rates between the Vicryl figure-of-8 and V-Loc barbed sutures

in our sample. However, the latter approach had less blood loss and shorter procedure duration and length of stay.

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