Original Article

New Continuous Barbed Suture Device with Stratafix for the Vaginal Stump in Laparoscopic Hysterectomy

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Abstract

Aims: Closure of the vaginal stump in total laparoscopic hysterectomy (TLH) performed by interrupted suture is time-consuming and requires sufficient experience. Stratafix (SF) is a new type of antibacterial monofilament absorbable suture which has multiple small anchors on the string surface. There is no information concerning the efficacy of SF for vaginal stump suture in minimally invasive hysterectomy.
Materials and Methods: We retrospectively evaluated the operative complications and SF (n = 20) advantages for the vaginal stump in TLH and compared with a cohort of patients with conventional sutures (n = 20). The differences in performance based on operators' skill levels were also considered.
Results: The time taken to close vaginal stump in the SF suture group was significantly lower than the conventional group (median times: 13.1 vs. 18.0 min, respectively; P = 0.038). Closure by a less experienced operator using SF suture was reduced by 7.2 min. The junior operator median vaginal suture time was only 2.6 min longer than the senior operator median time in SF suture group (P = 0.218), whereas an 8.4 min difference was recorded in the conventional suture group (P = 0.043). Total operation times did not significantly correlate with vaginal suturing techniques (median times: 126 vs. 145 min, respectively; P = 0.718). Complications regarding the vaginal stump closure techniques including organ injury, bleeding, wound separation, and pain did not occur in both groups.
Conclusions: SF suturing facilitates the vaginal stump closure in TLH without increasing the complications. SF allowed vaginal stump approximation and reduced the operative burden, especially in less experienced operators.

Keywords: Barbed suture, stratafix, vagina, stump, hysterectomy, laparoscopic-assisted surgery

Introduction

Total laparoscopic hysterectomy (TLH) has rapidly become the common uterine resecting approach in the past 20 years, not only for benign gynecologic disease but also malignant disease. Procedures have evolved and are easily performed through new technological developments. However, the closure of vaginal stump performed by interrupted suture is time-consuming and requires sufficient experience in TLH.

Stratafix (SF Symmetric PDS Plus®) is a new type of antibacterial monofilament absorbable suture which has multiple small anchors on the string surface. Small anchors strongly prevent separation of tissues and can be used for high-tension areas such as the fascial closure technique in laparotomy. Recently, SF has been used in other types of surgery including obstetrics and several categories of plastic surgery.[1,2] The use of barbed sutures has been introduced gradually in laparoscopic procedures including myomectomy. In laparoscopic myomectomy, reapproximation of the myometrium is the most time-consuming step, and unsatisfactory handling of the needle usually causes hemostasis. A comparison of SF and conventional suture for

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uterine wall closure in laparoscopic myomectomy revealed that overall operative time and suture time were significantly reduced, and less blood loss was recorded in the SF group. Assessment of adhesion in follow-up periods revealed no significant difference in both groups under transvaginal hydrolaparoscopy.[3] The systematic review for laparoscopic myomectomy also revealed the superior facilitation of barbed suturing than conventional suturing.[4]

The most important considerations regarding the administration of new devices for the vaginal stump closure are operative time, postoperative complications, and cost.[5] There is still a lack of information concerning the efficacy of SF for intracorporeal vaginal stump suture in minimally invasive hysterectomy. The purpose of this study was to assess the safety and feasibility of SF suturing for TLH in comparison to conventional interrupted suture.

Materials and Methods

We retrospectively evaluated the operative complications and performances with operative times, suture times, blood loss, and length of hospitalization of the SF ($n = 20$) suturing for the vaginal stump in TLH from April, 2017 to December, 2017, and compared with a cohort of patients with conventional sutures ($n = 20$) from November, 2016 to March, 2017. Eligible patients were scheduled for TLH regardless of diseases although the TLH treatments not covered by insurance were excluded. This study of TLH was conducted at Kagoshima University Hospital and Kagoshima Medical Center by two operators: a senior operator who is laparoscopic technical certified and a noncertified junior operator. The criteria for a certified operator are designated by the Japan Society of Gynecologic and Obstetric Endoscopy and Minimally Invasive Therapy. It is awarded to those who have been proven to safely and smoothly perform endoscopic surgery. The differences in performance based on operator skill level were also assessed. SF suture group was planned in able for each physician to perform surgery on ten patients. The surgical outcomes from this experimental cohort were compared with a cohort of standard vaginal stump suture (conventional suture group) performed by the same two operators in a clinical database. The number of performed surgeries by each doctor was identical in the SF group and the conventional suture group. Clinical data were collected by reviewing inpatient charts and operative records. Follow-up was commonly performed around 30 days postoperatively. Regarding the duration of suture times, the first handling of the needle to the last suture cut by scissors defined the timing. The operative time was measured between the first puncture of the trocar and the removal of the instrument after completion of the procedure.

Intergroup comparisons were performed with the Chi-square test for categorical differences and the Mann–Whitney U-test for continuous or ordinal data. $P < 0.05$ was considered to be statistically significant. All statistical analyses were performed on a personal computer with a statistical software package (SPSS for Windows, version 23; SPSS Inc., Chicago, IL, USA).

Procedures

The SF suture group suture procedures were as follows: the needle was inserted into the 6 o'clock position of the vaginal wall and exited from the right vaginal stump to affix its tab at the tail end [Figure 1a]. Reverse handling of the needle from the vesical side to the dorsal side was performed from the 3 to 9 o'clock position [Figure 1b]. For duplicated stump closure, backstitching from 9 to 3 o'clock was similarly added [Figure 1c and d]. All patients were administered the standard 30 cm stitch for vaginal stump closure. The Douglas peritoneum over the vaginal stump was repaired by uninterrupted suture. The same technique was used by both senior and junior operators in all of the SF suture group patients.

The conventional suture group procedures were as follows: techniques consisted of knot tying with interrupted absorbable (about 5 mm apart) sutures of 0 polyglactin 910 (Coated VICRYL® Plus, ETHICON). Half (10/20 patients) of the patients experienced opened peritoneum after the resected uterus was repaired by uninterrupted sutured.

Results

Characteristics were almost identical in each group [Table 1]. Almost half of the patients underwent endometrial cancer surgery including TLH, bilateral salpingo-oophorectomy, and sentinel navigation surgery in both groups. The median times of vaginal stump closure in the SF suture group

Table 1: Baseline characteristics

	[a]SF suture group ($n=20$)	Conventional suture group ($n=20$)	*P*
Median age, years (range)	51 (31-64)	54 (24-79)	0.253
Median BMI (range)	23.4 (19.4-31.2)	22.4 (20-27.9)	0.414
Vaginal delivery			0.736
None	7 (54%)	6 (46%)	
Present	13 (48%)	14 (52%)	
Operators			1.000
Junior	10 (50%)	10 (50%)	
Senior	10 (50%)	10 (50%)	
Diseases			0.824
Myoma	3 (50%)	3 (50%)	
Myoma+[b]CIN	2 (33%)	4 (67%)	
Endometrial hyperplasia	1 (33%)	2 (67%)	
Endometrial cancer	12 (55%)	10 (45%)	
Adenomyosis	2 (67%)	1 (33%)	

[a]SF, Stratafix, [b]CIN, Cervical intraepithelial neoplasia

were significantly lower than the conventional suture group (13.1 vs. 18.0 min, respectively; $P = 0.038$) [Table 2]. Closure by the junior operator using SF suture was reduced by 7.2 min compared to using conventional sutures, whereas there were no significant differences between the two groups performed by the senior operator. The junior operator median vaginal suture time was only 2.6 min longer than the senior operator in the SF suture group ($P = 0.218$), whereas there were an 8.4 min differences in the conventional suture group ($P = 0.043$). In patients undergoing the second sequence and fourth sequence performed by the junior operator in the SF group much more time was spent on the suturing procedure (25.1 min and 29.1 min, respectively) because the long stitch became entangled elaborately. Total operation times did not significantly correlate with vaginal suturing techniques (median operation times: 126 vs. 145 min, respectively; $P = 0.718$). Moreover, it is estimated that the time differences between the junior and senior operators will equal out after the experience of completing the procedure on ten patients [Figure 2].

Complications regarding the vaginal stump closure techniques including organ injury, bleeding, wound separation, and pain did not occur in both groups. Intraoperative vaginal deceleration due to removing a resected uterus through the vagina occurred in one patient in the SF group. All cases of complications were cured spontaneously and did not lead to serious conditions. Barbs which protruded from the vaginal stump into the vagina could not be seen after the operative examinations and no complaints of discomfort during sexual intercourse.

Discussion

The use of uninterrupted suturing for the vaginal stump is theoretically advantageous as a continuous stitch seems to reduce the closure time and completely approximate the

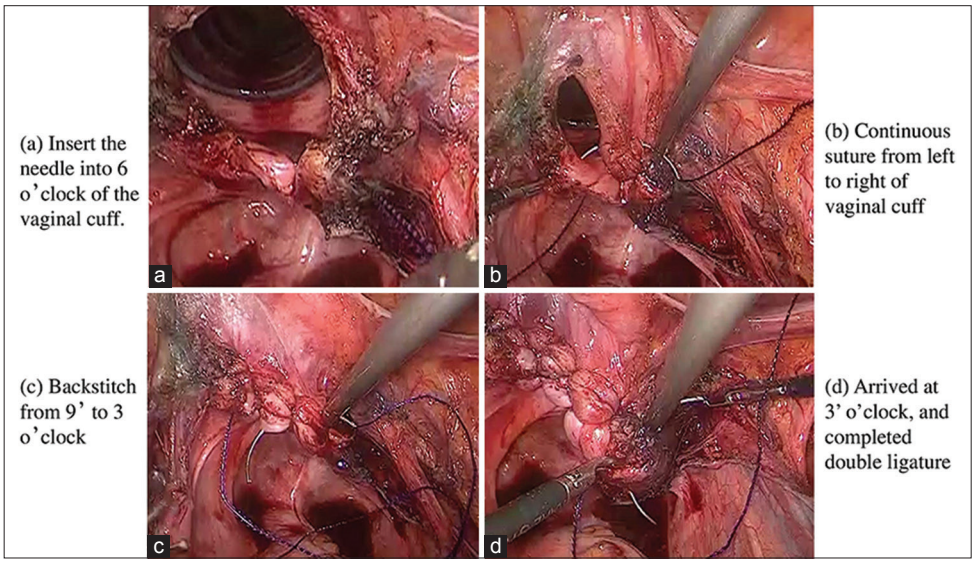

Figure 1: The needle was inserted into the 6 o'clock position of the vaginal wall (a), The needle from the vesical side to the dorsal side was performed from the 3 to 9 o'clock position (b), Backstitching from 9 to 3 o'clock (c), Arrived at 3 o'clock (d)

Table 2: Surgical outcomes and complications

	[a]SF suture group ($n=20$)	Conventional suture group ($n=20$)	*P*
Median vaginal stump suture times, minutes (range)	13.1 (7.5-29.1)	18.0 (9.5-53.5)	0.038
Senior operator	10.6 (7.5-13.7)	12.0 (9.5-15.6)	0.218
Junior operator	13.2 (9.4-29.1)	20.4 (11.2-53.5)	0.043
Median operation times, minutes (range)	126 (100-275)	145 (78-291)	0.718
Median blood loss, ml (range)	32.5 (5-460)	20 (5-500)	
Intraoperative complications	Vaginal deceleration: a patient	None	
Postoperative complications	Transient slight left hydronephroureter:[a]patient	Transient pelvic infection: a patient. Slight intraabdominal hematoma: a patient. Urinary tract infection:[a]patient	
Median length of hospitalization, days (range)	6 (3-15)	7 (5-17)	0.242

[a]SF, Stratafix

vaginal wall. However, conventional uninterrupted sutures often become loose because of difficulty maintaining tension. Loose suture causes bleeding and vaginal dehiscence complicated prolapses of the intestine in some cases. Therefore, we performed interrupted suturing with absorbable sutures in all cases for TLH. However, uninterrupted suturing for the vaginal stump is the most stressful procedures in TLH and requires practice to obtain suturing techniques.

We found that SF was a safer and easier technique than conventional interrupted sutures even when performed by a junior operator. Small anchors maintained the consistent tension of the vagina, eliminated the need for an assistant to follow the suture line, and did not cause postoperative complications including vaginal bleeding. It is known that the average duration of vaginal closure time by the senior operator was significantly shorter than that by the junior operator.[6] SF contributes to shorter vaginal stump suture times than conventional interrupted suturing, especially in junior operators. SF can easily achieve the shorter vaginal stump closure time in junior operators in collaboration with the experience of a small number of operations. However, a longer stitch often made it difficult to smoothly handle the needle, so we hope to introduce a new standard of shorter stitches.

There have been two types of barbed sutures: bidirectional device and a unidirectional device. Quill™ self-retaining system firstly introduced barbed suture devices for gynecological surgery in 2007. A needle is present at both suture ends, and barbs are made by cutting into the suture. Unidirectional devices are V-Loc™ and newer devices of SF. The characteristic of V-Loc™ barbs is dual-angle cut into the suture, whereas barbs of SF are connected to the suture core and geometrically patterned anchors. Barbs of the SF connected to the core may maintain strength over the other type of barbed suture which is created by cutting barbs, and this is the most important difference between SF and other barbed devices. Complete vaginal stump tissue close was achieved without losing suture traction after only one handling of the needle in SF, whereas other barbs require multiple handlings of the needle.

Although there was no report regarding the SF for the vaginal stump, other barbed suture devices have been assessed in some literatures.[4-14] Besides, almost reported with other barbed suture devices were retrospective analysis.[6,12] Comparative studies reviewed vaginal stump suture times and operative time and the estimated blood loss was even between barbed sutures and conventional sutures.[4] Einarsson *et al*.[6] demonstrated that mean vaginal stump closing times by attending staff were almost identical (attendings were 7.7 min in Quill™, and 6.5 min in Vicryl, respectively), and mean closing times by fellows/residents were longer but also even (13.1 min and 12.5 min, respectively). Attending staff vagina stump closure

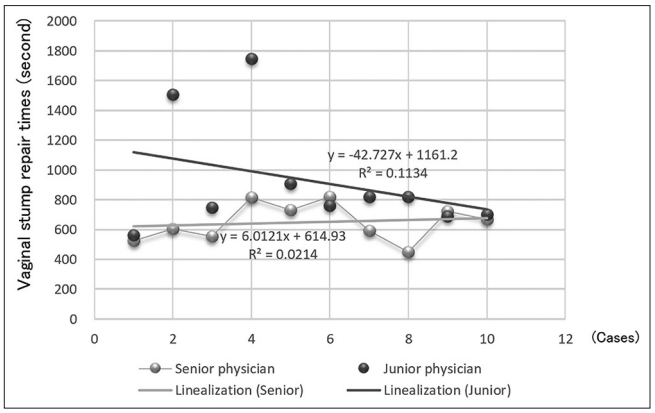

Figure 2: Regression analysis by sequence of operation

times were significantly faster than residents and fellows. Continuous suturing was employed with both the conventional suture and barbed suture, whereas our study using conventional suture was performed by interrupted suturing. Hence, the vaginal stump suture times were shorter than our study, and this may become difficult to reach significant by closure type. Most current articles are still reviewing the superiority of these techniques.[5] Some reports estimated the degree of technical difficulty and stated that barbed suture suturing was clearly easier than conventional suturing.[4]

In our SF group, the vaginal stump suture times took longer compared to other articles because our procedures added the backstitch and double stitch for avoiding wound dehiscence. The double stitch was achieved by backstitching from the 9 to 3 o'clock position in conjunction with the commonly performed continuous single stitch from the 3 to 9 o'clock position. Jeung *et al*.[15] evaluated the vaginal stump dehiscence of two suture techniques during TLH with the widely used interrupted figure-of-eight suture and the two-layer continuous suture. The rates of vaginal dehiscence were not significantly different in the two groups (1.6% in interrupted figure-of-eight suture group, 0.8% in two-layer continuous suture group, respectively; $P = 0.561$) However, the safety of single-layer continuous suture is not clearly proved, so we adopted the double stitch in SF for vaginal stump closure.

Wound healing and sexual function are another important consideration for postoperative vaginal closure outcomes. Although some reports described fewer dehiscences with barbed sutures,[7,8] a lot of research did not reach significant differences in both groups due to rarely experienced complications.[6,9-13] In our series, both groups did not experience wound dehiscence. At least, there have been no reports proving that the conventional suture is more superior than barbed sutures in wound dehiscence. A prospective study evaluated the postoperative changes in sexual function using the Female Sexual Function Index (FSFI).[6] The overall FSFI score was not significantly different in both groups, while

each item of desire and satisfaction in the Vicryl group was significantly superior to the barbed suture group.

Potential major complications regarding the administration of SF for the vaginal stump including bowel injury or obstruction due to adhesion, stump tissues necrosis, and bleeding did not occur in our series. There have been a small number of cases regarding the barbs tending to stick surrounding organs in other barbed suture devices.[14] However, these complications seem fewer in SF than other barbed suture devices because the anchors are tapered and blunt compared to other barbed suture devices. Vaginal stump dehiscence is one of the not negligible complications in reported cases, while our duplicated stump closures seem to contribute to the lack of experience in our patients.[4,5,7] Suture tying technique has many individual variation in vaginal stump closure. SF may bridge the individual variations by operators, and a decrease in the definitive surgical cost including the barbed suture material may be expected by reducing the operating room times. Recent and innovative less-invasive treatment with natural orifice transluminal endoscopic surgery is being introduced in Asia.[16-19] This technique carries many advantages: the benefit of no superficial wound, a decrease in patient discomfort and pain, and a lack of complications. Such positive recent technologies, including the administration of barbed sutures, contribute to ultimate less-invasive therapy in gynecology.

Conclusions

This research provides the first evidence that SF facilitates the ease and quickness of vaginal stump closure in TLH without increasing the complications. SF led vaginal stump well approximation and reduced the operative burden, especially in inexperienced operators for TLH techniques. However, there is currently limited detailed information on the use of SF for the vaginal stump. Therefore, further prospective extensive studies are necessary and warranted.

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Conflicts of interest

There are no conflicts of interest.

References

1. Hughes J, Ballard DH, Macieski F, Ho MT, Caldito G, Valiulis J, *et al.* Wound breakdown with stratafix *versus* monocryl suture in aesthetic and reconstructive plastic surgery: Data from a single surgeon. Am Surg 2017;83:e4-5.
2. Zayed MA, Fouda UM, Elsetohy KA, Zayed SM, Hashem AT, Youssef MA, *et al.* Barbed sutures versus conventional sutures for uterine closure at cesarean section; a randomized controlled trial. J Matern Fetal Neonatal Med 2017;1-8.
3. Giampaolino P, De Rosa N, Tommaselli GA, Santangelo F, Nappi C, Sansone A, *et al.* Comparison of bidirectional barbed suture stratafix and conventional suture with intracorporeal knots in laparoscopic myomectomy by office transvaginal hydrolaparoscopic follow-up: A preliminary report. Eur J Obstet Gynecol Reprod Biol 2015;195:146-50.
4. Tulandi T, Einarsson JI. The use of barbed suture for laparoscopic hysterectomy and myomectomy: A systematic review and meta-analysis. J Minim Invasive Gynecol 2014;21:210-6.
5. Smith K, Caceres A. Vaginal cuff closure in minimally invasive hysterectomy: A Review of training, techniques, and materials. Cureus 2017;9:e1766.
6. Einarsson JI, Cohen SL, Gobern JM, Sandberg EM, Hill-Lydecker CI, Wang K, *et al.* Barbed versus standard suture: A randomized trial for laparoscopic vaginal cuff closure. J Minim Invasive Gynecol 2013;20:492-8.
7. Siedhoff MT, Yunker AC, Steege JF. Decreased incidence of vaginal cuff dehiscence after laparoscopic closure with bidirectional barbed suture. J Minim Invasive Gynecol 2011;18:218-23.
8. Rettenmaier MA, Abaid LN, Brown JV 3rd, Mendivil AA, Lopez KL, Goldstein BH, *et al.* Dramatically reduced incidence of vaginal cuff dehiscence in gynecologic patients undergoing endoscopic closure with barbed sutures: A retrospective cohort study. Int J Surg 2015;19:27-30.
9. Bogliolo S, Nadalini C, Iacobone AD, Musacchi V, Carus AP. Vaginal cuff closure with absorbable bidirectional barbed suture during total laparoscopic hysterectomy. Eur J Obstet Gynecol Reprod Biol 2013;170:219-21.
10. Cong L, Li C, Wei B, Zhan L, Wang W, Xu Y, *et al.* V-loc™ 180 suture in total laparoscopic hysterectomy: A retrospective study comparing polysorb to barbed suture used for vaginal cuff closure. Eur J Obstet Gynecol Reprod Biol 2016;207:18-22.
11. Kim JH, Byun SW, Song JY, Kim YH, Lee HJ, Park TC, *et al.* Barbed versus conventional 2-layer continuous running sutures for laparoscopic vaginal cuff closure. Medicine (Baltimore) 2016;95:e4981.
12. Ardovino M, Castaldi MA, Fraternali F, Ardovino I, Mosca L, Colacurci N, *et al.* Bidirectional barbed suture in total laparoscopic hysterectomy and lymph node dissection for endometrial cancer: Technical evaluation and 1-year follow-up of 61 patients. J Laparoendosc Adv Surg Tech A 2013;23:347-50.
13. Bassi A, Tulandi T. Evaluation of total laparoscopic hysterectomy with and without the use of barbed suture. J Obstet Gynaecol Can 2013;35:718-22.
14. Donnellan NM, Mansuria SM. Small bowel obstruction resulting from laparoscopic vaginal cuff closure with a barbed suture. J Minim Invasive Gynecol 2011;18:528-30.
15. Jeung IC, Baek JM, Park EK, Lee HN, Kim CJ, Park TC, *et al.* A prospective comparison of vaginal stump suturing techniques during total laparoscopic hysterectomy. Arch Gynecol Obstet 2010;282:631-8.
16. Lee CL, Wu KY, Huang CY, Cheng C, Han CM, Yen CF. Subtotal hysterectomy by natural orifice transluminal endoscopic surgery. Gynecol Minim Invasive Ther 2017;6:195-8.
17. Yoshiki N. Review of transvaginal natural orifice transluminal endoscopic surgery in gynecology. Gynecol Minim Invasive Ther 2017;6:1-5.
18. Li PC, Ding DC. Transvaginal natural orifice transluminal endoscopic surgery hysterectomy in a woman with uterine adenomyosis and multiple severe abdominal adhesions. Gynecol Minim Invasive Ther 2018;7:70-3.
19. Hong MK, Wang JH, Chu TY, Ding DC. Laparoendoscopic single-site hysterectomy with ligasure is better than conventionalvaginal hysterectomy. Gynecol Minim Invasive Ther 2014;3:78.