SCIENTIFIC PAPER JSLS

Bidirectional Barbed Suture: An Evaluation of Safety and Clinical Outcomes

Jon I. Einarsson, MD, MPH, Thomas T. Vellinga, BSc, Andries R. Twijnstra, MD, Niraj R. Chavan, MD, Yoko Suzuki, MD, James A Greenberg, MD

ABSTRACT

Objective: To evaluate the safety and efficacy of using bidirectional barbed suture in laparoscopic myomectomy (LM) and total laparoscopic hysterectomy (TLH).

Methods: This was a case series of clinical outcomes following 172 consecutive LM and TLH cases over a 1-year period conducted at a university teaching hospital. It included 172 women (ages 17 to 81), requiring a myomectomy or hysterectomy for symptomatic uterine fibroids, pelvic pain, or abnormal uterine bleeding; 117 women underwent TLH and 55 women underwent LM. Patients were contacted over the phone 6 months after surgery to inquire about number of days of postoperative vaginal bleeding, visits to the hospital due to bleeding, dyspareunia, and other potential complications.

Results: For TLH, the average duration of surgery was 109 minutes, average uterine weight was 256 grams (range, 18 to 1242), and average blood loss was 71mL. In LM, average duration of surgery was 125 minutes, average weight of fibroids was 252g, average number of fibroids removed was 4.0, and average blood loss was 159mL. Seven percent of patients and 8% of their partners had persistent dyspareunia after surgery. There were no conversions to laparotomy.

Conclusions: The use of bidirectional barbed suture appears to be safe for closing the vaginal cuff in a TLH and for closing the hysterotomy site during a laparoscopic myomectomy.

Key Words: Barbed suture laparoscopic hysterectomy myomectomy.

Boston, Massachusetts, USA (Drs Einarsson, Chavan, Suzuki, Greenberg).

Amsterdam, Netherlands (Mr Vellinga, Dr. Twijnstra).

Address correspondence to: Jon I. Einarsson, MD, MPH, Brigham and Women's Hospital, 75 Francis St, ASB 1-3, Boston, MA 02118, USA. Telephone: (617) 525-8582, Fax: (617) 975-0900, E-mail: jeinarsson@partners.org

No Disclosures or conflicts of interest

DOI: 10.4293/108680810X12924466007566

INTRODUCTION

Barbed suture is a relatively new concept in gynecologic surgery. The Quill SRS bidirectional barbed suture (Angiotech Pharmaceuticals, Inc. Vancouver BC, Canada) was FDA approved for soft tissue approximation in 2004[1] and has been commercially available in the United States since 2007.

Bidirectional barbed sutures are created by cutting barbs into the suture with the barbs facing in an opposite direction to the needle. The barbs change direction at the midpoint of the suture[2] **(Figure 1)**, and needles are swaged onto both ends of the suture. Due to its decreased effective diameter, the straight-pull tensile strength of barbed suture is rated one suture size greater than smooth suture. For example, a 0 barbed suture equals a 2-0 smooth suture. The anchoring of bidirectional barbed suture resists migration and can be conceptualized as a "continuous interrupted" suture without knots and has been shown to have at least equal tissue holding performance as comparable knot anchored suture has.[3,4] This offers several advantages. Since bidirectional barbed sutures self-anchor and are balanced by the countervailing barbs, no knots are required. Furthermore, barbed suture self-anchors at every 1mm of tissue, yielding more consistent wound opposition. Finally, knotless barbed suture can securely reapproximate tissues with less time, cost, and aggravation.[5,6]

We first used bidirectional barbed suture for gynecologic surgery in March of 2008[5] and have since then completed over 300 laparoscopic cases using this material. Because the application of bidirectional barbed suture is fairly new in gynecologic endoscopy, we were interested to evaluate perioperative clinical outcomes of these patients. Our primary goal was to establish that bidirectional barbed suture can be used safely in gynecologic laparoscopy, specifically when closing the vaginal cuff during a total laparoscopic hysterectomy and when closing a hysterotomy at the time of a laparoscopic myomectomy.

METHODS

This is a retrospective cohort study of 172 consecutive patients who underwent either a total laparoscopic hys-

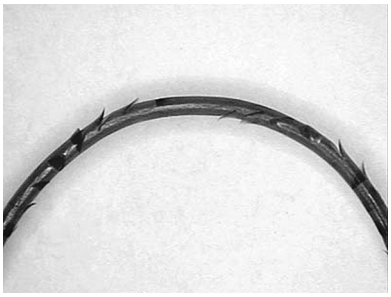

Figure 1. Bidirectional barbed suture with barbs that change direction in the middle.

terectomy or a laparoscopic myomectomy in the period of March 2008 until March 2009. The technique of total laparoscopic hysterectomy has been previously described.[7] For vaginal cuff closure, a 0 polydioxone (PDO) bidirectional barbed suture on a 36-mm half-circle taper point needle was used. We initially used one-half of a 14-cm x 14-cm suture with a LapraTy clip on the distal end. The repair is started at the distal end of the vaginal cuff, taking care to incorporate the uterosacral ligament into the initial bite and is continued proximally until the other uterosacral ligament is incorporated into the repair. Regardless of suture material used, it is important to obtain a full-thickness bite with a 1-cm margin on the vagina mucosa on each bite. We make sure to incorporate the rectovaginal fascia, vaginal mucosa, and pubocervical fascia in each bite. More recently, we have been using the 7-cm x 7-cm 0 PDO, because this is now available with the 36-mm half-circle taper point needle. Here, we start the closure in the middle of the cuff and take each needle to the opposite end of the cuff. The uterosacral ligaments are similarly incorporated, and the suture is cut without a knot or a LapraTy clip.

Briefly, our laparoscopic myomectomy technique is as follows. Access to the pelvis is generally via an umbilical camera port and 2 parallel operative ports on the left side. A third operative port may be used on the right side if required. The uterus is infiltrated with dilute vasopressin (20 units in 40mL of saline), taking care to use no more than 10 units each time.[8] We generally prefer to create a horizontal incision into the uterus by using the Harmonic scalpel (Ethicon Endo-Surgery, Cincinnati, OH). The fibroid is then dissected out of the uterus with the help of generous traction with a tenaculum and countertraction with an atraumatic grasper as well as the Harmonic scalpel, as needed. In case of an inadvertent entry into the uterine cavity, the endometrial defect is closed with a running 2-0 polyglactin 910 smooth suture, taking care to avoid suture entry into the uterine cavity. The hysterotomy is then closed in layers by using a 14-cm x 14-cm 0 PDO bidirectional barbed suture on a 36-mm half-circle taper point needle. If the hysterotomy is longer than 8cm, we prefer to use the 24-cm x 24-cm bidirectional barbed suture. Tacking the first needle to the opposite anterior abdominal wall helps to avoid suture tangling. The deepest layer is closed using the first needle, and the second needle is used to close the more superficial layer and the serosa if possible. The needles are cut and a LapraTy clip can be applied if the suture is used beyond the barbed portion of the suture. Sometimes 3 to 4 layers are needed to close a deep myometrial defect. 2/0 Monoderm bidirectional barbed suture can also be used for the serosa either continuously or as a baseball stitch. The hysterotomy site is generally covered with an adhesion barrier (Interceed).

Patients were generally discharged home the day of surgery or the following day and were seen in the office for a postoperative visit 3 weeks to 4 weeks after surgery. In addition, we contacted all the patients who underwent a TLH approximately 6 months to 12 months after surgery to inquire about postoperative bleeding, pain during intercourse, partner discomfort during intercourse, and the need for any provider intervention after surgery as a result of vaginal bleeding or other causes. All patients undergoing a TLH or laparoscopic myomectomy were considered eligible for participation in this study. The patients were contacted by sending a letter introducing the study and were offered a voluntary "opt-out" option by calling the study office. Approximately 2 weeks later, the patients received a phone call from our study staff where we asked standardized questions regarding these outcomes as outlined above. Finally, a copy of the questions was also sent by mail, and patients had the option of answering the questions by mail via a self-addressed postmarked envelope that was sent to them. Nonrespondents were recontacted via a phone call or E-mail to seek their responses for inclusion in the study. Subjects who failed to respond after the second attempt were dropped from consideration in the analysis of the medium-term follow-up for clinical outcomes following TLH surgery.

All of the cases were either performed or supervised by the first author (JIE). In many instances, residents or fellows acted as the primary surgeon for most of the case, including the suturing of the vaginal cuff or the hysterotomy site. The study was reviewed and approved by the Partners Institutional Review Board.

RESULTS

The patient demographics are shown in **Table 1**. The perioperative outcomes for total laparoscopic hysterectomy are shown in **Table 2**. For TLH, the average duration of surgery was 109 minutes, average uterine weight was 256 grams (range, 18 to 1242), and average blood loss was 71mL. One TLH patient sustained a bladder injury that was recognized intraoperatively and repaired laparoscopically without further incident. One TLH patient required vaginal cuff resuturing due to superficial cuff disruption. There was one case of suspected vaginal cuff cellulitis. No cases of full-thickness cuff dehiscence occurred.

The perioperative outcomes for laparoscopic myomectomy are shown in **Table 3**. In LM, average duration of surgery was 125 minutes, average weight of fibroids was 252g, average number of fibroids removed was 4.0, and average blood loss was 159mL. One patient in the myomectomy group required a repeat laparoscopy due to a small bowel obstruction that was unrelated to the myomectomy procedure itself.

The overall incidence of complications is shown in **Table 4**. Two patients required a blood transfusion. Eighteen patients had minor postoperative complications, such as a urinary tract infection and bacterial vaginitis.

Table 5 displays the findings of the medium-term survey among patients who underwent TLH. Vaginal bleeding and spotting was minimal and short in duration; however, a few patients reported dyspareunia as well as male dyspareunia.

Table 1.
Patient Demographics

	Total Laparoscopic Hysterectomy (n = 117)	Myomectomy (n = 55)
Characteristics		
Age (y)	44.98 (8.05)	40.38 (7.02)
Body mass index	29.92 (7.60)	26.17 (5.90)
Parity	1.6 (1.3)	0.5 (0.9)
Premenopausal n (%)	102 (87)	49 (92.5)
Prior laparotomy n (%)	54 (46)	21 (39)
Indication		
Uterine fibroids n (%)	67 (57)	54 (100)
Pelvic pain n (%)	84 (72)	38 (70)
Endometriosis n (%)	13 (11)	1 (2)
AUB n (%)	83 (71)	24 (44)
Ovarian cyst n (%)	20 (17)	5 (9)

Data are presented as Mean (SD) unless otherwise specified.
AUB = abnormal uterine bleeding.

Table 2.
Perioperative Outcomes for Total Laparoscopic Hysterectomy (N = 117)

	Mean ± SD
Duration of surgery (min)	109.21 ± 44.52
Estimated blood loss (mL)	71.03 ± 157.02
Uterine weight (g)	256.65 ± 222.97
Hospital stay (days)	1.11 ± 0.79

DISCUSSION

Suture material has undergone 2 major revolutions: the introduction of a process for the sterilization of "catgut" in 1907[9] and the introduction of absorbable, synthetic materials in 1970s.[10] With each of these advances, the smooth configuration of the suture material and the need for securing knots remained unchanged. Bidirectional barbed suture introduces a new paradigm in which the tension on suture material is evenly distributed across the length of the filament rather than at the knots on the end. In this regard, in vitro, bidirectional barbed suture has been shown to outperform same-size conventional suture material in both tensile strength and wound holding capacity.[2]

In the present series of 172 consecutive patients, we have demonstrated that bidirectional barbed suture can be used safely and effectively in patients undergoing a total laparoscopic hysterectomy and laparoscopic myomectomy. In our experience, this suture material facilitates suturing by preventing backwards sliding of the suture, thereby enabling continuous suturing without

Table 3.
Perioperative Outcomes for Laparoscopic Myomectomy (N = 55)

	Mean ± SD
Duration of surgery (min)	125.47 ± 55.30
Estimated blood loss (mL)	158.68 ± 252.35
Number of fibroids removed	4.01 ± 4.21
Weight of fibroids (g)	252.07 ± 196.43
Hospital stay (days)	0.73 ± 0.36

Table 4.
The Overall Incidence of Complications (n = 172)

	N %
Intraoperative Complications	
Bladder injury	1 (0.6)
Postoperative Complications	
Blood transfusion	2 (1.2)
Pelvic hematoma	2 (1.2)
Infection incision site	5 (3)
Urinary tract infection	11 (6.5)
Vaginal yeast infection	2 (1.2)
Episodes of vaginal bleeding	2 (1.2)
Small bowel obstruction	2 (1.2)
Vaginal cuff cellulitis	1 (0.6)
Superficial cuff disruption	1 (0.6)
Total	28 (16.3)

the need for suture locking or to have another surgeon follow the suture to maintain the tension between throws. The initial version had a 7-cm "smooth" or nonbarbed segment next to the needle. This resulted in sliding of the suture if the repair extended beyond the barbed segment of suture. To counteract this, we utilized the LapraTy clip to secure the smooth segment of suture. The use of LapraTy in this setting was off-label, as LapraTy is indicated for use with 2/0, 3/0, and 4/0 Vicryl only. Despite this, we did not have any complications utilizing the LapraTy clips in this setting. With the advent of a second generation of Quill suture where the barbs extend all the way to the needle, the use of the LapraTy clip is not required.

This study represents the first 172 consecutive patients to have bidirectional-barbed suture utilized for this indication. A single experienced laparoscopic surgeon was scrubbed for all cases, though residents and fellows with varying surgical experience performed many of the closures under direct supervision. Furthermore, the patients who underwent a total laparoscopic hysterectomy were followed for a mean of 10.2 months, at which time most of the complications after laparoscopic hysterectomy will have presented themselves.[11] We did not have a single case of full-thickness vaginal cuff dehiscence using the barbed suture for cuff closure. This compares favorably with recent reports of a 4.1% to 4.9% incidence of full-thickness cuff dehiscence after a total laparoscopic and robotic hysterectomy using conventional suturing material.[12,13] Unfortunately, the retrospective nature of this study may present outcomes in an overly positive light, since some of the patients may not be able to remember all the potential complications or problems they may have had in the immediate postoperative period (recall bias). In addition, the potential benefits of barbed suture to facilitate laparoscopic suturing, such as shortened operating time and increased suturing efficiency, were not critically evaluated in this paper and await future evaluation.

We believe this is the first study to evaluate male dyspareunia following a laparoscopic hysterectomy. We are thus uncertain whether the 8% rate of male dyspareunia is related to the use of barbed suture or if it is related to other factors. We did not determine the rate or nature of dyspareunia or male dyspareunia prior to surgery. Female dyspareunia is multifactorial in nature,[14] and we did not fully evaluate the causes of dyspareunia in this patient population. Of note, the suture material studied in this trial was polydioxone (PDO.) This suture has a relatively long time to complete mass absorption (180 to 240 days) compared with more commonly used materials, such as polyglactin-910 (56 to 70 days).[15] It is possible that both the male and female dyspareunia encountered in this study are a result of residual suture material that had not yet reabsorbed. We are planning a prospective randomized trial in the near future to further evaluate suturing times, postoperative outcomes, dyspareunia, and male dyspareunia.

CONCLUSION

We have demonstrated that bidirectional-barbed suture can be used safely and effectively for laparoscopic sutur-

Table 5.
Short-term Follow-up of TLH Patients (n = 82)

	N(%)
Length of follow-up (months) mean (SD)	10.2 (3.4)
Days of bleeding/spotting after TLH mean (SD)	9.4 (14.3)
Hospital revisits due to bleeding	6 (7.3)
Vaginal cuff tear, resutured	1
Treatment with silver nitrate	1
Clinical examination only	4
Dyspareunia after surgery	10 (13.7)
Persistent dyspareunia 6 months after surgery	5 (6.8)
Partner dyspareunia after surgery	6 (8.2)

ing when laparoscopic cuff closure and laparoscopic hysterotomy closure are being performed. Based on our experience, we believe that the further development and incorporation of this suture material into clinical practice should be actively explored.

References:

1. http://www.accessdata.fda.gov/cdrh_docs/pdf4/k042075.pdf. 2004. Accessed July 12, 2010.

2. Leung JC. Barbed suture technology: Recent advances. *Medical Textiles*. 2004 October;26-27:62–80.

3. Rashid RM, Sartori M, White LE, Villa MT, Yoo SS, Alam M. Breaking strength of barbed polypropylene sutures: rater-blinded, controlled comparison with nonbarbed sutures of various calibers. *Arch Dermatol*. 2007;143:869–872.

4. Rodeheaver GT, Pineros-Fernandez A, Salopek LS, et al. Barbed sutures for wound closure: In vivo wound security, tissue compatibility and cosmesis measurements. *Society for Biomaterials 30th Annual Meeting Transactions*. 2004;229:232.

5. Greenberg JA, Einarsson JI. The use of bidirectional barbed suture in laparoscopic myomectomy and total laparoscopic hysterectomy. *J Minim Invasive Gynecol*. 2008;15:621–623.

6. Moran ME, Marsh C, Perrotti M. Bidirectional-barbed sutured knotless running anastomosis v classic Van Velthoven suturing in a model system. *J Endourol*. 2007;21:1175–1178.

7. Einarsson JI, Suzuki Y. Total laparoscopic hysterectomy: 10 steps toward a successful procedure. *Rev Obstet Gynecol*. 2009;2:57–64.

8. Frishman G. Vasopressin: if some is good, is more better? *Obstet Gynecol*. 2009;113:476–477.

9. Dietz UA, Kehl F, Hamelmann W, Weisser C. On the 100th anniversary of sterile catgut kuhn: Franz Kuhn (1866-1929) and the epistemology of catgut sterilization. *World J Surg*. 2007;31: 2275–2283.

10. Laufman H, Rubel T. Synthetic absorbable sutures. *Surg Gynecol Obstet*. 1977;145:597–608.

11. Garry R, Fountain J, Brown J, et al. EVALUATE hysterectomy trial: a multicentre randomized trial comparing abdominal, vaginal and laparoscopic methods of hysterectomy. *Health Technol Assess*. 2004;8:1–154.

12. Kho RM, Akl MN, Cornella JL, Magtibay PM, Wechter ME, Magrina JF. Incidence and characteristics of patients with vaginal cuff dehiscence after robotic procedures. *Obstet Gynecol*. 2009; 114:231–235.

13. Hur HC, Guido RS, Mansuria SM, Hacker MR, Sanfilippo JS, Lee TT. Incidence and patient characteristics of vaginal cuff dehiscence after different modes of hysterectomies. *J Minim Invasive Gynecol*. 2007;14(3):311–317.

14. van Lankveld JJ, Granot M, Weijmar Schultz WC, et al. Women's sexual pain disorders. *J Sex Med*. 2010 Jan;7(1 Pt 2):615–631.

15. Chu CC, von Fraunhofer JA, Greisler HP. Wound Closure Biomaterials and Devices. CRC Press, Danvers, MA USA;1997:61.