

Long-term urinary functional outcome of vesicourethral anastomosis with bidirectional poliglecaprone (Monocryl®) vs. barbed polyglyconate suture (V-Loc™ 180) in robot-assisted radical prostatectomy

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Abstract

Introduction: We aimed to evaluate urinary continence recovery following robot-assisted radical prostatectomy (RARP) using monofilament poliglecaprone (Monocryl®) suture vs. barbed suture (V-Loc™ 180) during vesicourethral anastomosis (VUA).

Methods: In this prospective, observational cohort, data were collected on 322 consecutive patients. All patients underwent continuous, bidirectional, single-layer running anastomosis with either 3.0 monofilament suture (n=141) or 3.0 barbed suture (n=181). The primary outcome was continence recovery defined as time to 0 pad at one, three, six, 12, and 24 months following surgery.

Results: Continence rates were significantly better with monofilament VUA at all followup time points up to one year. Median time to continence was one month vs. five months in the monofilament group vs. barbed group, respectively (p<0.001). Continence rates in monofilament suture vs. barbed group at one, three, six, 12, and 24 months were 56% vs. 26% (p<0.001), 73% vs. 36.4% (p<0.001), 84.4% vs. 60.2% (p<0.001), 90.8% vs. 71.9% (p<0.001), and 93.5% vs. 87.1% (p=0.1), respectively. Anastomosis time was shorter in the barbed group, with a median of 23 vs. 30 minutes (p<0.001). Patients anastomosed with Monocryl suture had smaller prostate weight (median 42.5 g vs. 50 g; p<0.001) and harbored less advanced disease (T2a–c 76.6 vs. 74%; p=0.01) relative to patients treated with V-Loc 180 suture. However, in a multivariate Cox logistic regression analyses, independent predictors of continence recovery were suture type (hazard ratio [HR] 53; 95% confidence interval [CI] 0.41–0.68; p=0.02) and prostate size (HR 0.99; 95% CI 0.98–0.99; p<0.001).

Conclusions: Barbed VUA contributed to delayed continence recovery compared to monofilament poliglecaprone suture during the first year post-RARP. However, no statistically significant difference was recorded at two years post-RARP. These results warrant special attention, especially with the widespread use of barbed suture in recent years.

Introduction

Robot-assisted radical prostatectomy (RARP) has been widely adopted since it was first promoted more than a decade ago.¹ Several predictive risk factors for continence recovery have been identified, including patient age, prostate size, neurovascular bundle preservation, membranous urethral length, uroflow stop test, and technical aspects of vesicourethral anastomosis (VUA).^{2–6}

Initially, VUA in laparoscopic radical prostatectomy used interrupted sutures.⁷ Subsequently, Van Velthoven et al introduced the use of bidirectional 3.0 polyglycolic acid running suture with one end dyed and the other end undyed.⁸ They reported a shorter anastomosis time and no perioperative complications compared to historic cohorts with interrupted sutures.

During the era of laparoscopic radical prostatectomy, different anastomotic sutures were traditionally used, including the braded suture type polyglactin-910 (Vicryl®; Ethicon, J and J Medical, Somerville, NJ, U.S.) and monofilament suture type poliglecaprone-25 (Monocryl®, J and J Medical, Somerville, NJ, U.S.). Monocryl has gained additional popularity with RARP due to its smooth texture and ease of use for running VUA. Since its introduction in 2009, bidirectional barbed suture (V-Loc™ Wound Closure Device, Covidien, Mansfield, MA, U.S.) has been widely used due to several advantageous properties, including the ability to hold tissue tension and avoid knot-tying, a decrease in the risk of a urine leak, and shorter anastomotic time.^{9,10} However, there is a paucity of data examining long-term continence recovery with barbed suture. The aim of this study is to explore the impact on continence recovery of barbed suture compared to monofilament suture in VUA post-RARP.

Methods

Study population characteristics

Following institutional review board approval, the current retrospective study was conducted from a prospectively collected RARP database. Between January 2006 and May 2015, a total of 322 consecutive patients underwent RARP for clinically localized prostate cancer by a single surgeon (AEH) at Hôpital du Sacré Coeur de Montréal, Montreal, QC, Canada. All data were documented in a standardized sheet at the time of surgery and during followup visits. Approximately 80% of patients had a minimum of two years' followup. No patient had previous endoscopic prostate surgery or pelvic radiation.

Objectives and endpoints

The primary endpoint of the study was to test postoperative continence recovery among patients undergoing VUA with barbed suture compared to monofilament suture. Continence was defined as 0 pad usage per day, which was recorded at one, three, six, 12, and 24 months following surgery using a self-administered questionnaire. Patients are initially followed on the sixth week after surgery with prostate-specific antigen (PSA), uroflow test, and post-void residual urine volume to exclude obstruction. They are then followed every three months for one year, and every six months for the subsequent four years, then yearly thereafter with PSA, Sexual Health Inventory for Men (SHIM) score, and modified International Prostate Symptom Score (IPSS), including additional questions on how many pads per day patient is using (0, one liner, one pad, two pads, three or more pads).

Covariates

Baseline characteristics were collected from the database. Age at surgery, PSA level, pathological prostate size, estimated blood loss, and anastomosis time were coded as continuous variables. Pathological stage was categorized into four groups: T2a–b, T2c, T3a, and T3b–T4, using TNM seventh edition classification. Pathological Gleason grade was stratified into four groups: ≤6, 3+4, 4+3, and 8–10. Bladder neck reconstruction and nerve preservation were also included.

Anastomosis surgical technique

Patients were grouped according to the type of sutures used for VUA during RARP: the bidirectional 3 0 Monocryl vs. the bidirectional V-Loc 180 suture. The Monocryl suture was used in the first 141 consecutive patients treated between January 2006 and January 2009, whereas the V-Loc 180

suture was used in the subsequent 181 patients treated between January 2009 and May 2015. Both arms underwent the same athermal robotic technique.^{11,12}

The anastomoses techniques for both study arms followed a modified Van Velthoven technique (REF) and consisted of applying two stitches at 6 o'clock of the bladder outside-in, then inside-out on the urethral stump. Additional sutures were placed on each side, at 5 and 7 o'clock, respectively, before the bladder was synched down. Thereafter, both mucosal edges of the bladder and urethra were approximated before further running the continuous sutures. The latter was performed in anti-clockwise fashion on the right and clockwise on the left side. Both arms had single running anastomosis without a separate Rocco posterior reconstructive layer. However, all V-Loc 180 group had the posterior bladder retrotrigonal layer incorporated with the anastomosis and deeper throws on the first couple urethral stitches to incorporate the so-called urethrectalis muscle. All cases were tested at the end of the anastomosis with 120–180 ml normal saline bladder filling to rule out a leak. All patients had the catheter removed on postoperative day 7 without cystogram. Neurovascular bundle-sparing and bladder neck preservation was attempted whenever feasible.

Statistical analyses

Descriptive statistics focused on frequencies and proportions for categorical variables. Means, medians, and interquartile ranges (IQR) were reported for continuous variables. The Mann-Whitney test and Chi-square test were used to compare statistical significance differences in medians and proportions, respectively.

First, continence rates at one, three, six, 12, and 24 months were compared between both suturing types. Subsequently, the log-rank test was used to compare continence rates between the two study arms. Finally, univariate and multivariate Cox-regression analyses were fitted to predict the effect of baseline clinical, operative, and pathological characteristics, as well as the type of suture on postoperative urinary continence rate.

All statistical tests were performed using the R software environment for statistical computing and graphics (Vienna, Austria, version 3.0.1). All tests were two-sided with a significance level set at $p < 0.05$.

Results

Baseline clinical, pathological, and operative characteristics stratified according to anastomotic suture type are summarized in Table 1. A total of 141 (44%) patients had anastomotic Monocryl suture and 181 (56%) patients had V-Loc 180 anastomotic suture. Median age, pathological Gleason grade distribution, and median estimated blood loss, as well

Table 1. Perioperative baseline characteristics of patients treated with robotic-assisted radical prostatectomy (RARP)

Patient characteristic	Polyglecaprone suture, mean (median) n=141	Barbed suture, mean (median) n=181	p
Age (years)	60.6 (61)	61 (61)	0.7
BMI			
Normal	26 (18.4)	36 (19.9)	0.04
Overweight	70 (49.6)	64 (35.4)	
Obese	28 (19.9)	42 (23.2)	
Unknown	17 (12.1)	39 (21.5)	
PSA (ng/ml)	6.5 (5.2)	7.1 (6)	0.002
Prostate volume (gm)	46 (42.5)	52.3 (50)	<0.001
Pathological stage			
T2a–b	21 (14.9)	52 (28.7)	0.01
T2c	87 (61.7)	82 (45.3)	
T3a	25 (17.7)	36 (19.9)	
T3b–T4	8 (5.7)	11 (6.1)	
Gleason score			
≤6	26 (18.4)	24 (13.3)	0.1
3+4	90 (63.8)	111 (61.3)	
4+3	13 (9.2)	15 (8.3)	
8–10	12 (8.5)	31 (17.1)	
Anastomosis time (min)	31.6 (30)	24.5 (23)	<0.001
Blood loss (ml)	336 (300)	325 (300)	0.5
Bladder neck reconstruction			
No	131 (92.9)	173 (95.6)	0.3
Yes	10 (7.1)	8 (4.4)	
Nerve preservation			
Complete	94 (66.7)	105 (58)	0.4
Partial	36 (25.5)	57 (31.5)	
No	11 (7.8)	19 (10.5)	
Pads usage*			
Yes	6/141 (4.2%)	12/152 (8%)	0.2
No	138/141 (97.4%)	140/152 (92%)	

*The number of pads usage at the end of the first year. BMI: body mass index; PSA: prostate-specific antigen.

as the proportion of patients who underwent bladder neck reconstruction and/or nerve preservation were comparable between both groups. However, patients anastomosed with Monocryl suture had smaller prostate weight (median 42.5 g vs. 50 g; $p<0.001$) and harbored less advanced disease (T2a–c 76.6 vs. 74%; $p=0.01$) relative to patients treated with V-Loc 180 suture. Similarly, lower PSA level (5.2 vs. 6; $p=0.002$) and longer anastomosis time (30 vs. 23 minutes; $p<0.001$) were found in the Monocryl group compared to the V-Loc 180 group. No bladder neck contracture or anastomotic stricture were identified in either cohort.

Postoperative urinary continence recovery rates were highly statistically significant between the two study groups favoring Monocryl suture at one month (Monocryl 56 vs. V-Loc 180 26%; $p<0.001$), three months (73 vs. 46; $p<0.001$), six months (84 vs. 60%; $p<0.001$), and 12 months (91 vs. 72%; $p<0.001$) after surgery (Fig. 1, Table 2). However,

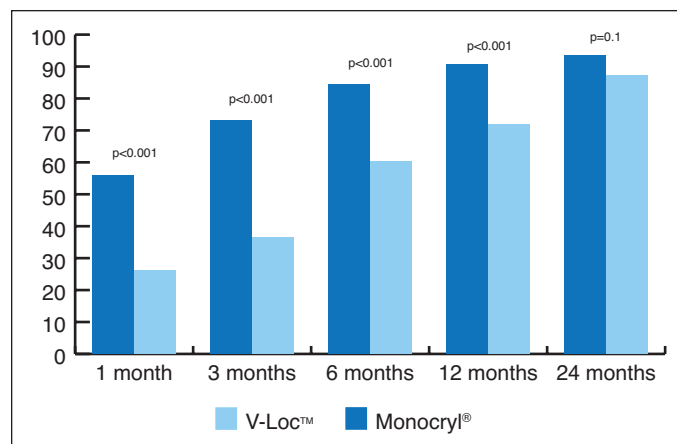


Fig. 1. Clustered columns chart shows the comparison between Monocryl® and V-Loc™ 180 continence rates at 1, 3, 6, 12, and 24 months.

the difference in postoperative continence rate wasn't statistically significant between the two groups at 24 months post-surgery (93.6 vs. 87.1%; $p=0.1$). The median time to continence in the Monocryl arm was one month compared to five months for the V-Loc 180 group ($p<0.001$). There were no anastomotic strictures or bladder neck contracture. No urine leak was identified on JP drain postoperatively.

In multivariable Cox-regression analyses (Table 3) after controlling for all potential confounders, suture type (hazard ratio [HR] 0.53; $p<0.001$) and prostate weight (HR 0.99; $p=0.02$) were both independent predictors for postoperative continence after RARP. However, date of surgery, age, body mass index, PSA level, pathological stage and grade, estimated blood loss, bladder neck reconstruction, and nerve-sparing were not predictors of postoperative continence after RARP (all $p>0.2$).

Discussion

In the past decade, RARP has gained worldwide acceptance in the treatment of clinically localized prostate cancer. VUA represents a pivotal step during prostatectomy. In general, VUA should be manipulated gently and sutured with absorbable sutures in a watertight, tension-free fashion to limit urinary leak, reduce morbidity, and provide early continence recovery.

Recently, barbed sutures were introduced as a technically advantageous suture in laparoscopic and robot-assisted radical prostatectomy. While barbed suture has been shown to be comparable to traditional sutures in term of postoperative urinary leak and safety, there is a paucity of data on the long-term continence recovery in patients sutured with barbed sutures compared to the traditional monofilament sutures.^{10,13-15} We, therefore, conducted a single-institution study to address this issue. Our results showed that barbed suture was associated with a delayed continence recovery relative to monofilament suture (HR 0.52; confidence interval

Table 2. Continence rates, 0 pad, at 1, 3, 6, 12, and 24 months after robotic-assisted radical prostatectomy according to anastomotic suture type

Suture type	1 month n=322	3 months n=322	6 months n=312	12 months n=294	24 months n=257
Polyglecaprone (Monocryl®)					
Continent, n (%)	79 (56%)	103 (73%)	119 (84.4%)	128 (90.8%)	132 (93.5%)
Incontinent, n (%)	62 (42%)	38 (27%)	22 (15.6%)	13 (9.2%)	9 (6.4%)
Barbed (V-Loc™ 180)					
Continent, n (%)	47 (26%)	84 (36.4%)	103 (60.2%)	110 (71.9%)	101 (87.1%)
Incontinent, n (%)	134 (74%)	97 (53.6%)	68 (39.8%)	42 (28.1%)	15 (12.9 %)
p	<0.001	<0.001	<0.001	<0.001	0.1

[CI] 0.41–0.66; $p < 0.001$) during all scheduled visits in the first year following surgery. In multivariable Cox regression analyses, Monocryl suture was an independent predictor of continence recovery (HR 0.53; CI 0.41–0.68; $p < 0.001$).

The physical properties of barbed suture differ from Monocryl suture. First, the extended dissolve time of the V-Loc 180 biomaterial is longer than Monocryl (half-life 7–14 days), at 180 days vs. 90 days; respectively.^{16–19} This

could contribute to the delayed continence recovery in the barbed group due to the risk of an inflammatory response to foreign body material, encrustation, and stretch of the urethral sphincter complex. Second, the breaking strength retention of the suture (tensile strength of suture in vivo) is prolonged in the V-Loc 180 material, with 65% of the initial strength at nine months compared to 20–30% of initial strength at the second week of the undyed (30–40% dyed)

Table 3. Univariable and multivariable Cox logistic regression analysis predicting independent variable for time to 0-pad after RARP

Covariants	Univariable		Multivariable	
	HR (95% CI)	p	HR (95% CI)	p
Age	0.98 (0.96–1)	0.06	0.99 (0.97–1.01)	0.5
BMI				
Normal	Ref.	Ref.	Ref.	Ref.
Overweight	0.95 (0.68–1.32)	0.8	0.9 (0.65–1.26)	0.5
Obese	0.88 (0.61–1.27)	0.5	0.88 (0.6–1.29)	0.5
Unknown	0.76 (0.51–1.13)	0.2	0.82 (0.55–1.24)	0.4
PSA	0.99 (0.96–1.02)	0.6	1 (0.97–1.03)	0.9
Prostate size	0.99 (0.98–0.99)	0.002	0.99 (0.98–0.99)	0.02
Pathological stage				
T2a–b	Ref.	Ref.	Ref.	Ref.
T2c	1.05 (0.78–1.41)	0.7	0.97 (0.72–1.31)	0.8
T3a	0.84 (0.58–1.24)	0.4	0.81 (0.54–1.23)	0.3
T3b–T4	1.3 (0.76–2.23)	0.3	0.97 (0.5–1.88)	0.9
Gleason score				
6	Ref.	Ref.	Ref.	Ref.
3+4	0.81 (0.58–1.13)	0.2	0.79 (0.55–1.12)	0.2
4+3	0.9 (0.55–1.49)	0.7	0.93 (0.53–1.62)	0.8
≥8	0.93 (0.6–1.44)	0.7	1.18 (0.60–2.02)	0.6
EBL	1 (1–1)	0.6	1 (1–1)	0.5
Bladder neck reconstruction				
No	Ref.	Ref.	Ref.	Ref.
Yes	0.91 (0.54–1.52)	0.7	1.05 (0.61–1.84)	0.9
Nerve preservation				
Complete	Ref.	Ref.	Ref.	Ref.
Partial	0.98 (0.75–1.29)	0.9	1.13 (0.84–1.5)	0.4
No	0.71 (0.46–1.09)	0.1	0.79 (0.49–1.28)	0.3
Type of anastomosis				
Monocryl	Ref.	Ref.	Ref.	Ref.
V-Loc	0.52 (0.41–0.66)	<0.001	0.53 (0.41–0.68)	<0.001

BMI: body mass index; CI: confidence interval; EBL: estimated blood loss; HR: hazard ratio; PSA: prostate-specific antigen.

Monocryl materials; at one week, strength is at 50–60% undyed (60–70% dyed). Persistence of suture tensile strength for a prolonged time at close proximity to external urethral sphincter may compromise the external sphincter function and blabber neck after surgery.^{16–19} Finally, the presence of valves on the V-Loc 180 suture might contribute to micro-infarctions and strangulation of the muscular component of the sphincter after application.

In a retrospective study, Polland et al compared the V-Loc 180 suture with the standard 3.0 monofilament and showed no difference in continence recovery between the study and control groups at six weeks (52% and 48%, respectively) and at six months (88% and 84%, respectively). They included 84 patients in a mixed-consecutive method rather than formal randomization with a high chance of selection bias in the study. The primary endpoints were to evaluate the efficacy during the surgery and perioperative complications.²⁰ Hemal et al conducted a prospective pilot study of 50 patients comparing the same type of sutures and reported the safety and efficacy of barbed suture intraoperatively. In the immediate postoperative period, none of the patients had symptomatic urine leak, retention, or anastomotic stricture. However, they did not look at continence recovery outcome longitudinally.²¹ William et al documented contrast leak in the barbed suture arm after randomization with a control group (Monocryl) based on cystogram. The rate of extravasation on day 8 following surgery was higher in the barbed group (20.0% vs. 2.8%; $p=0.01$), with longer catheterization time (11.1 days vs. 8.3 days; $p=0.04$), and greater suture cost per case ($p<0.001$). During the study, they modified their technique to avoid overtightening and, consequently, the incidence of subsequent cystogram extravasation was reduced to 6.3% in the barbed group.²²

Another randomized, controlled trial conducted by Sammon et al assessed barbed suture vs. the standard monofilament. Continence was assessed six weeks post-RARP by a modified questionnaire mailed to patients to assess continence for the past week only. Although the functional outcomes were equivalent at the one time point in both groups, the study was limited by the small number of patients.¹⁰ Massoud et al prospectively evaluated the use of V-Loc running suture with a single-needle driver vs. interrupted polyglactin sutures.²³ Their results favored the V-Loc arm in terms of shorter anastomosis time and feasibility of the reported single-needle driver technique. However, the difference in continence rates (0 pad) at 12 months was not statistically significant between both groups (97.5% V-Loc vs. 95% polyglactin; $p=0.37$). While the V-Loc arm had a non-significant prolonged healing time over control, their results lacked the detailed continence recovery in the first year post-surgery.¹⁹

Despite the evolution in the surgical techniques of VUA in the literature and the shorter VUA times seen over the past

two decades, the reported continence recovery rate is still under-reported and not fully examined.^{23,24} With regard to sutures, additional research is necessary, specifically looking at continence recovery at different time points. Further work-up on the nature of the biochemical and physical properties of barbed sutures could improve the results of continence recovery and in so doing, improve patient quality of life following RARP and satisfaction with the da Vinci surgical system, particularly in the current era of active surveillance.

There are several advantages in this study that merit mention. First, it is the only study examining long-term followup for continence recovery following RARP. Second, while most previous studies have concentrated on perioperative surgical outcomes (i.e., VUA time, contracture, and urinary leakage at the anastomotic site), we longitudinally evaluated postoperative functional outcome using a self-administered questionnaire. However, the study is not devoid of limitations. The two arms were not always comparable in terms of some baseline characteristics, including body mass index, prostate size, and tumor stage. This is the result of the selection of best patient characteristics in the initial experience of the operating surgeon. However, the multivariate analysis confirmed the independence of suture type for predicting continence recovery. Additionally, we expected a delayed continence recovery with the initial experience at the time of monofilament usage but found the opposite result in favor of monofilament suture. Furthermore, due to sequential inclusion of patients in the study, all patients in the monofilament arm completed the followup period for 24 months, whereas there was a dropout in the followup of the barbed suture arm. About 84% and 64% of the barbed suture arm cohort completed followup at the end of 12 months and 24 months, respectively. Although there was no dropout at the initial two visits, the continence rate is still more favorable in the monofilament arm. A further confirmatory study is needed in the future to clarify the association.

Conclusions

Urinary incontinence is a common adverse effect after radical prostatectomy, which can be upsetting for patients and their quality of life. Although robotic surgery hastens early continence recovery, selecting the optimal suture type is still of clinical relevance for early continence. The current study proves the superiority of monofilament over barbed suture in the recovery of urinary continence. Nevertheless, more research is needed in the form of randomized studies to confirm these results.

Competing interests: Dr. Zorn has received honoraria as a proctor/lecturer for Greenlight from Boston Scientific; and participated in the clinical trial of WATER2 with aquablation supported by Procept Biorobotics. The remaining authors report no competing financial or personal interests related to this work.

This paper has been peer-reviewed

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