STUDY TITLE: Barbed Suture versus Non-Barbed Suture for Posterior Colporrhaphy: A Randomized Controlled Trial

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BACKGROUND

Pelvic organ prolapse (POP) is a growing concern for the aging female population, and symptomatic women often require surgical intervention. Approximately 200,000 surgical procedures for POP are performed annually in the United States. This number is anticipated to increase with the growth in the aging population.[1] Surgical prolapse repairs are often categorized into either mesh augmented or native tissue repairs. During a native tissue repair, the surgeon uses a woman's natural tissue to repair the prolapse without augmenting the repair with synthetic mesh.

Women often have post-operative pain with native tissue posterior colporrhaphy.[2] Native tissue posterior repairs are performed to address symptomatic posterior compartment prolapse, defects in the rectovaginal fibromuscularis, and/or a widened genital hiatus. This type of repair may improve obstructed defecatory dysfunction and bulge symptoms, but can be associated with postoperative pelvic pain and dyspareunia.[3] Paraiso et al evaluated three surgical techniques for posterior colporrhaphy (site-specific, midline plication, and porcine graft) and found no difference in overall symptom improvement, quality of life, and post-operative sexual function.[4] Regardless of the technique used, a posterior colporrhaphy can cause considerable postoperative pain and can contribute to de novo dyspareunia in 9-20% of women.[2, 4-6] Most studies evaluating pain after posterior colporrhaphy tend to focus on various methods of analgesia and surgical technique rather than the suture materials used.[7]

Suture choice may contribute to postoperative pain at the time of posterior colporrhaphy. There are few studies evaluating suture in the posterior compartment with no defined standard suture material for posterior colporrhaphy. Luck et al found that suture erosion and wound dehiscence were noted after using a permanent suture during posterior colporrhaphy; consequently, permanent suture is now seldomly used.[8] Available studies, when comparing subjective bulge and quality of life outcomes, do not demonstrate superiority of one suture type over the other.[9-11] Delayed absorbable suture has the benefit of retaining tensile strength for approximately 3 months. Delayed absorbable suture material itself, however, can remain in place for 6-8 months.[12] Barbed delayed absorbable suture has unique properties. The small barbs on the delayed absorbable sutures allow for even distribution of suture strength along the incisional closure without the need for knots. These properties may decrease postoperative pain by decreasing knot burden. Barbed suture has been successfully applied to vaginal cuff closure, myomectomy, sacrocolpopexy mesh attachment, and closure of bowel and bladder injuries with demonstrated reduced operative times. [13-16] To date, no studies have evaluated the impact of barbed suture on postoperative pain or surgical time after posterior colporrhaphy.

STUDY PURPOSE

To compare the use of barbed suture versus non-barbed suture at the time of posterior colporrhaphy and describe an innovative suturing technique for posterior repair using barbed suture.

STUDY OBJECTIVES

Primary Objective

1. To compare delayed absorbable barbed suture versus non-barbed delayed absorbable suture at the time of posterior repair on post-operative posterior compartment pain scores, as measured by the Visual Analog Scale (VAS), at 6 weeks
2. To describe an innovative technique for posterior repair using barbed suture

Secondary Objectives

1. To compare VAS pain scores in the posterior compartment at 6-months and 12-months
2. To evaluate operative time for posterior repair in minutes
3. To evaluate suture burden and pelvic pain on examination of the posterior compartment
4. To evaluate pain versus the length of a repair in cm measured by length of defect from hymen to most proximal delayed absorbable suture
5. To evaluate postoperative patient quality of life (QoL) using Pelvic Floor Distress Inventory- 20 (PFDI-20), specifically the Colorectal-Anal Distress Inventory-8 (CRADI-8) and the Pelvic Organ Prolapse Distress Inventory- 6 (POPDI-6)
6. To evaluate postoperative sexual function using the PISQ-12
7. To evaluate cost of delayed absorbable suture choice based on sutures used
8. To evaluate anatomical failure of posterior compartment at 6-weeks and 12-months
9. To evaluate subjective failure of posterior compartment at 6-weeks, 6-months, 12-months
10. To evaluate differences in adverse outcomes using modified Clavien-Dindo classification system

We plan to perform a prospective analysis of secondary outcomes outlined above at 12 months.

HYPOTHESIS

Delayed absorbable barbed suture will have less post-operative pain in the posterior compartment than delayed absorbable non-barbed suture at the time of posterior repair, as measured by VAS at 6 weeks.

NULL HYPOTHESIS (H_0)

There will be no difference in post-operative pain in the posterior compartment between delayed absorbable barbed suture and delayed absorbable non-barbed suture, as measured by VAS at 6 weeks.

STUDY DESIGN AND METHODS

Randomized controlled superiority trial offered to patients undergoing posterior colporrhaphy for pelvic organ prolapse at Atrium Health. This study will be conducted at four clinical sites:

1. Women's Center for Pelvic Health (Mercy), Atrium Health, Charlotte, NC

2. One Day Surgery (ODS) Center, Atrium Health, Charlotte, NC
3. Women's Center for Pelvic Health (Cabarrus), Atrium Health, Concord, NC
4. Carolinas Medical Center, Atrium Health, Charlotte, NC

Human Subject Research and Informed Consent

Each subject will be required to sign an Institutional Review Board (IRB) approved consent form prior to beginning any study-related interventions or assessments. The informed consent form will describe the study in detail. Additionally, the study consent form will disclose the planned uses of study data, as well as potential risks to the subjects. Each prospective subject will have the objectives of the study explained to them prior to enrollment. The subject will be given an opportunity to ask questions and decide whether or not to participate. Copies of the signed informed consent form will be provided to the subjects, and the originals will be stored with the research records for this study at the Mercy study center.

Subjects have the right to:

- Voluntarily participate in the study
- Withdraw or refuse participation in the study at any point without questioning
- Understand the objectives of the study
- Understand the risks and benefits of the study
- Have their confidentiality maintained

Participant (Subject) Screening and Point of Enrollment

Subjects scheduled to undergo posterior colporrhaphy with or without perineorrhaphy will be identified and screened against inclusion and exclusion criteria. If potential subjects meet the requirements for the study, they will be eligible to be invited to participate. Subjects will be consented for study enrollment by physicians, fellow physicians, nurse practitioners, physician's assistants, and/or a research nurse prior to surgery at either their pre-operative visit or the morning of surgery. Subjects will be randomized to one of the two treatment groups in the operating room prior to starting the surgical procedure.

Provider and Clinical Staff Training

To ensure consistent posterior colporrhaphy technique, the principal investigator will provide in-service educational video to all participating providers who will be performing surgery. Educational review will include review of suture materials being used and specific repair protocol. All clinical staff, including nursing and physicians, will receive in-service training about the study protocol and guidelines. Providers performing follow-up exams will be educated on pelvic organ prolapse quantification (POP-Q) examination technique, and a standardized method to digitally palpate suture burden and myofascial trigger points using a standardized pictorial tool. Personnel administering or collecting interviews/measurement scales/questionnaires will be trained on how each interview/measurement scale/questionnaire should be completed.

Inclusion Criteria

1. Women
2. Age 18yo or older
3. English speaking
4. Undergoing posterior colporrhaphy with or without perineorrhaphy
    a) Concomitant surgical procedures allowed

Exclusion Criteria

1. Documented allergy or contraindication to use of suture material (polydiaxonone, dioxanone, glycolide or trimethylene carbonate)
2. Prior mesh in posterior compartment
3. Planned colpocleisis
4. Current or prior rectovaginal fistula
5. Planned sacrospinous ligament fixation procedure
6. Chronic pelvic pain diagnosis
7. Chronic narcotic medication use (daily narcotic use for ≥ 3 weeks before surgery by review of NC Controlled Substances Reporting System (CSRS))
8. Active vulvodynia
9. Non-English speaking
10. Inability to provide informed consent
11. Planned concomitant anal or rectal surgery

Study Withdrawal

Subjects may withdraw from the study at any point in time. Documentation of the reason for withdrawal will be captured in the data collection forms. There will be no risk to subjects that choose to withdraw from the study.

Preoperative Period

All eligible patients planned to undergo posterior colporrhaphy will be identified preoperatively, screened, and approached for participation in the study. Concomitant pelvic reconstructive surgical procedures allowed. Subjects who do not meet the inclusion and exclusion criteria will be considered screen failures. Screen failures will be captured, and the cause for screen failure will be documented.

If a patient agrees to participate in study, baseline demographic information, as well as medical and medication history will be collected. A set of preoperative baseline questionnaires will also be administered, including the PFDI-20, PSQI-12, and a baseline pain assessment using VAS. If a prior POP-Q exam is not documented in the chart, a POP-Q and myofascial trigger point exam will be completed at this visit.

Consent will either be obtained at the preoperative visit. Or, if they are undergoing a virtual preoperative visit, they will receive an email with consent to review and then sign consent on the day of surgery.

Perioperative and Surgery Period

All subjects will receive routine preoperative intravenous antibiotic prophylaxis based on standard hospital protocols. All subjects will receive standard of care anesthetic and prophylactic medications as determined by anesthesia providers.

Intervention: Eligible subjects will be randomized using a computer-generated randomization scheme, with patients assigned in a blinded 1:1 ratio, stratified by concurrent minimally invasive abdominal surgery, to either:

Group 1: Intervention

1. **Barbed suture**: 2-0 dioxanone, glycolide and trimethylene carbonate (V-Loc 90™Medtronic), delayed absorbable, monofilament, barbed-suture
   (1) Violet dyed
   (2) Tapered needle

Group 2: Control

2. **Non-barbed suture**: 2-0 polydioxanone (PDS® Ethicon™) delayed absorbable, monofilament, non-barbed suture
   (1) Violet dyed
   (2) Tapered needle

The allocation sequence will be in sealed, opaque envelopes. An envelope will be retrieved in the operating room. The OR circulating nurse will assemble the appropriate intervention suture materials. The envelope will then be labeled and given back to the research nurse.

Procedures will be performed by 4 fellowship trained, board-certified female pelvic reconstructive surgeons and 3 fellows in training. Residents will not participate in posterior repair. Subjects will be positioned in dorsal lithotomy with the use of adjustable stirrups. The patient will be prepped and draped as is standard of care at our institution, either for vaginal, or combined vaginal and abdominal surgery depending on planned concomitant surgery. After surgical timeout, a Foley urinary catheter will be placed. Concomitant procedures will be performed in the order that the surgeon deems necessary.

The posterior repair will be repaired in the following standardized fashion, which is most similar to the technique described by prior studies.[3, 12, 17-18] First, the posterior compartment vaginal epithelium and perineal body will be injected with local anesthetic with epinephrine (0.25% Marcaine with 1:200000 epinephrine) for tissue dissection and hemostasis prior to incision. This local anesthetic may be diluted with normal saline to a final volume deemed appropriate by the surgeon. The vaginal epithelium is then incised as far proximal as is indicated to correct the rectocele. The vaginal epithelium is dissected off the underlying connective tissue to expose the rectocele to the arcus tendineous rectovaginalis or as far as clinically indicated. Prior to starting the posterior colporrhaphy plication, a sequentially numbered opaque sealed envelope will be opened by the circulating nurse, revealing the study group allocation**.** Sutures will then be placed

on the sterile field to be used for plication of the rectovaginal fibromuscularis. The surgeons will then proceed with plication of the fibromuscularis with unidirectional barbed suture in a running unlocked fashion (intervention) or non-barbed (control) in an interrupted fashion, depending on prior randomization. 5 knots will be tied for each pass of interrupted non-barbed suture. If a second layer of closure is needed the same suture material must be used as allocated by randomization. If a non-midline site-specific defect corrected, suture type and number of throws must be documented. vaginal epithelium is trimmed as is deemed necessary by the surgeon. The vaginal skin is closed with an undyed 2-0 polyglactin (Vicryl) suture down to the hymenal plate**.** The bulbocavernosus and the transversus perineal muscles are reunited in the midline with inverted sutures of undyed 2-0 polyglactin (Vicryl) in either interrupted fashion. If the perineal epithelium is closed, it will be closed using an undyed 2-0 polyglactin (Vicryl) suture in a subcuticular fashion. For polyglactin, 4 knots will be tied as indicated. Knots are tied inside the hymeneal plane when possible to avoid pain caused by knots in the perineal body. If vaginal packing placed, it will be placed at the conclusion of the procedure in the operating room at the surgeon's discretion (Figure 1).

Although both sutures are dyed violet, the barbed suture is a knotless unidirectional barbed suture that must be used in a running fashion. For this reason, surgeons performing the posterior repair will not be blinded to allocation of study suture material. We feel this will not significantly impact our results as patients will remain blinded and study personnel collecting outcome data will also remain blinded. The study subject and all other postoperative clinical staff (recovery nurses and floor nurses) will be blinded to study arm.

Figure 1: Technique of posterior repair[19]

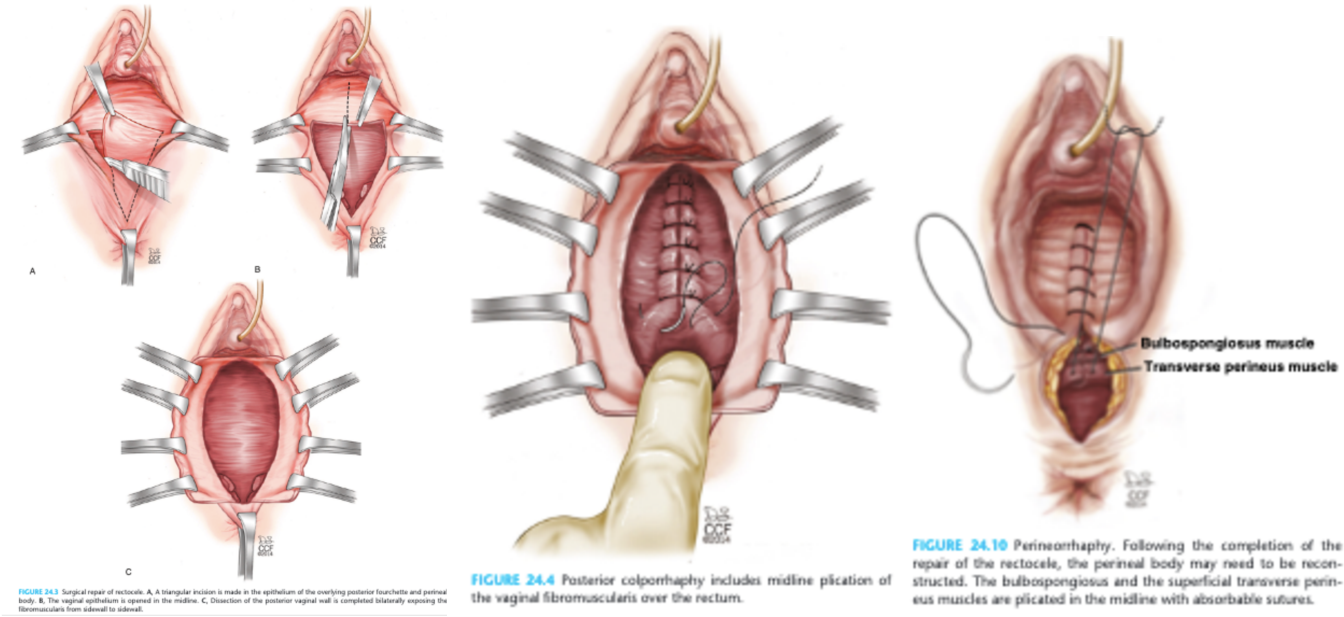


FIGURE 24.3 Surgical repair of rectocele. A, A triangular incision is made in the epithelium of the overlying posterior fourchette and perineal body. B, The vaginal epithelium is opened in the midline. C, Dissection of the posterior vaginal wall is completed bilaterally exposing the fibromuscularis from sidewall to sidewall.

FIGURE 24.4 Posterior colporrhaphy includes midline plication of the vaginal fibromuscularis over the rectum.

FIGURE 24.10 Perineorrhaphy. Following the completion of the repair of the rectocele, the perineal body may need to be reconstructed. The bulbospongiosus and the superficial transverse perineus muscles are plicated in the midline with absorbable sutures.

Intervention: Subjects randomized to the barbed suture (Group 1) will have rectovaginal fibromuscularis plicated in a running, unlocked fashion as described above.

Control: Subjects randomized to the non-barbed suture (Group 2) will have rectovaginal fibromuscularis plicated in an interrupted fashion as described above. The polydioxanone suture was chosen as a control due it being both an institutional and national standard for suture and technique being used in the posterior compartment. Polydioxanone was chosen over polyglactin, due to its similarity to the barbed suture material and expert opinion recommendation that delayed absorbable suture be use in the posterior compartment for colporrhaphy (Culligan 2005). Additionally, prior study protocols have used polydioxanone. [11,17-18] This also allows us to control for specific suture properties, including: delayed absorbable nature (180-210 days for polydioxanone vs. 90-110 days for barbed suture), suture size, suture color (violet), synthetic monofilament, and tapered needle type (Appendix 4, Figure 1).

Immediate Postoperative Period

All surgery patients at our institution routinely receive enhanced recovery after surgery (ERAS) protocol for pain management by a department standardized order set pre and postoperatively, unless there is a contraindication.

Most patients at our institution are discharged the same day of surgery. Discharge criteria include independent ambulation, tolerate an oral diet, adequate pain control with oral medications, and voiding trial. If a vaginal pack is placed, it is removed prior to discharge. There will be no changes in discharge criteria for this study.

The standard ERAS calls for a multimodal pain regimen postoperatively. Patients are discharged home on the following regimen: ibuprofen 600-800 mg every 8 hours, oxycodone/ acetaminophen (Percocet) 5mg/325 mg or or hydrocodone/acetaminophen (Norco/Lortab) 5mg/325mg 1 pill every 4-6 hours as needed and, and may also receive gabapentin 100-600mg TID for 5 days. They are instructed to take MiraLAX, Colace, or another stool softener as needed. They receive counseling at preoperative visit on how to take these medications. Pain medications may be slightly altered based on allergies or intolerances.

Patients are given a set of standard postoperative instructions, which include general precautions, nothing per vagina for 6-8weeks, no lifting greater than 10 pounds until 6-8weeks.

6 weeks +/- 3 weeks

Subjects will be scheduled for a postoperative follow up visit at approximately 6 weeks. At this visit they will have a structured postoperative interview and pelvic examination, including POP-Q, standardized assessment of suture burden and myofascial trigger points. They will also complete a VAS, validated questionnaires: PFDI-20 subscales (CRADI-8, POPDI-6). We will review bowel regimen and pain medications used during the past 6-weeks. We will also perform an adverse events screening.

6months +/- 2 month

Subjects will be called at approximately 6 months after their original surgery. During this phone call they will have a structured interview and complete VAS, validated

questionnaires: PFDI-20 subscales (CRADI-8, POPDI-6), PSQI-12 (if sexually active). We will also perform adverse events screening. The VAS/pain assessment form will be given to patient at their 6-week visit for their 6-month phone call. Another copy will be sent with a pre-paid return envelope approximately 2-weeks prior to anticipated phone call follow-up as a reminder.

12 months +/- 3 month

Subjects will be scheduled for a postoperative follow up visit at approximately 12 months after their original surgery. At this visit they will have a structured postoperative interview and pelvic examination, including POP-Q, assessment of suture burden and myofascial trigger points. The will also complete VAS, validated questionnaires: PFDI-20 subscales (CRADI-8, POPDI-6), PSQI-12 (if sexually active). We will perform adverse events screening.

Randomization:

A biostatistician in the Center for Outcomes Research and Evaluation (CORE) at Atrium Health will generate a randomization sequence using SAS Enterprise Guide 7.1 (SAS Institute Inc., Cary, NC, USA). A permuted block randomization scheme will be used to assign patients in a 1:1 ratio to intervention or control. Randomization will be stratified by presence or absence of concurrent minimally invasive abdominal surgery. We feel this stratification of randomization sequence is necessary because we anticipate patients who undergo vaginal surgery alone versus vaginal and concurrent minimally invasive abdominal surgery experience a different quality and severity of postsurgical bowel function and pain.

The study will be blinded such that both study subjects and investigators collecting postsurgical outcome data will be masked to treatment allocation and block size randomization. The surgeon performing the posterior repair will be unblinded. The surgical technician, operating room circulating nurse, and statistician will also not be blinded, but will have no contact with the patients.

The operating room nurse will pull the study suture materials- consisting of either barbed suture or non-barbed suture. They will also pull the standardized suture materials for posterior repair as listed above, which includes caliber of suture and needle type for each suture used.

After the posterior dissection is completed, the randomization will take place. The sequentially numbered opaque sealed envelope will be opened by the circulating nurse, revealing the study group allocation. The study suture will then be opened by the operating room nurse and placed on the surgical field.

DATA COLLECTION AND MANAGEMENT:

Case report forms will be developed by the investigators. Data will be collected prospectively per the schedule in Table 1. All study data will be recorded by research staff and securely maintained at the Mercy study site. The data flow will consist of paper data collection for

eligibility assessment, baseline data, randomization, intervention group, primary and secondary outcomes, adverse events, and protocol deviations.

Data will be entered by study staff into Research Electronic Data Capture (REDCap) database that will be stored on a secure server at Atrium Health. REDCap is a secure, web-based application designed to support data capture for research studies, providing: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources. [20] Data will be entered into REDCap within 30 business days of collection.

Each subject will have a unique identification number to which only the principal and sub-investigators will have access. The data collection spreadsheet will not contain any patient identifiers and will be password protected. The master list that links the patients and their study identification number will be stored separately from the database. All collected information will be stored separately on a password protected hard drive. A back up copy of the file will be stored on a password protected hospital network drive. All hard copies of study data will be stored in a locked cabinet in the office of the research nurse, which will also be locked.

Table 1. Data Collection Schedule

	Pre-op	Surgery (Intra-op)	6 Week Follow-up	6 Month Phone call	12 Month Follow-up
Informed Consent	x				
Medical History	x				
Medication review	x				
***Other Demographics**	x				
****Surgery**		x			
Randomization		x			
Hospital length of stay			x		
Pain scale (VAS)	x		x	x	x
Post-op pain medication use			x		
*****Examination**	x		x		x
PFDI-20	x		x	x	x
PSQI-12	x			x	x
Adverse events screen		x	x	x	x
Suture and Operative cost			x		

*Other demographic data includes: Age, Race, Body Mass Index (BMI), Stage of posterior compartment prolapse (per pre-operative POP-Q exam), post-menopausal status (yes/no), vaginal hormone replacement therapy (HRT) (yes/no), smoking status (packs per day), if sexually active (yes or no)

**Surgery data includes: surgeon, concurrent surgeries performed, type of suture used in posterior colporrhaphy, number of layers for posterior colporrhaphy (midline plication only), isolated defect (yes/no), suture used for isolated defects, number of barbed or non-barbed suture packets used for posterior colporrhaphy, number of transverse suture passes for barbed suture during posterior colporrhaphy, number of interrupted suture passes for non-barbed suture during posterior colporrhaphy, amount of remaining barbed or non-barbed suture left over after posterior colporrhaphy (cm), length of repair (cm) of posterior colporrhaphy, if packing placed (yes/no), total

surgical duration (minutes), surgical duration of posterior colporrhaphy with or without perineorrhaphy (minutes), total estimated blood loss (EBL), any surgical complications.

*** Examination: pre-operative (POP-Q examination, myofascial pain), post-operative (POP-Q examination, evaluation of suture burden and myofascial pain).

Source of records to be reviewed:

- Canopy electronic medical record (EMR)
- Research nurse coordinator will identify charts to be reviewed based on addition of subject's name and medical record number to a general data sheet

Confidentiality of data

Electronic data will be stored to safe-guard confidentiality using a password protected computer. Principal investigator, Co-investigator, Research Coordinator nurse, and statisticians will have access to harvested patient data. Harvested patient data will be stored until final statistical analysis completed and manuscript accepted and published.

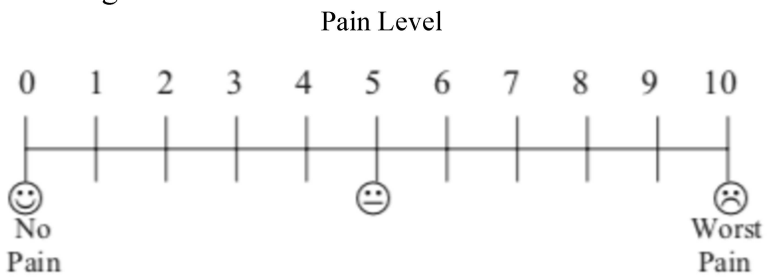
OUTCOME MEASURES

Primary Outcome Measure

The primary outcome will be assessed pain after posterior colporrhaphy, specific to the posterior compartment, using a VAS (Figure 2). The VAS is a validated scale that is ranges from 0-100mm. 0mm is equivalent to "no pain" and is located on the left. 100mm is equivalent to "worst possible pain" and is located on the right. Subjects are asked to draw a vertical line on the scale that corresponds to their level of pain.

The VAS will be collected by blinded study personnel at multiple time points. Baseline scores will be collected at the preoperative visit or in the preoperative holding area. Pain scores will then be collected at the 6-week postoperative visit, the 6-month phone call and 12-month post-operative visit. The pain will be based on subjects average pain level over the past 3 days. The scores will be collected either in office or by phone calls by a blinded research nurse or one of the study investigators.

Figure 2: Visual Analog Scale[21]



Secondary Outcome Measures

Suture burden and myofascial pain: This will be determined by standardized pelvic examination using digital palpation and/or visualization of knots/suture, as well as palpation of myofascial trigger points performed at 6-weeks and 12-months. Recorded using a diagram in the medical record at follow-up visits (Appendix 4, Figure 2).

Surgical time for posterior repair (posterior colporrhaphy with or without perineorrhaphy): We will record total time of procedure start to finish in minutes, as well as total time of posterior repair from start to finish in minutes.

Length of surgical repair (posterior colporrhaphy): We will measure the total length of the posterior colporrhaphy in centimeters (cm) (this will be measured from the hymen (most distal point) to the level of the first suture pass (most proximal)) at completion of the repair.

Postoperative sexual function measures: We will record patient responses to the validated PISQ-12 questionnaire at preoperative visit, 6-months, and 12-months in the medical record at follow-up visits (Appendix 2, Figure 2).

Postoperative patient quality of life (QOL) measures: We will record patient responses to the validated PFDI-20 subscales (CRADI-8, POPDI-6) at preoperative visit, 6-weeks, 6-months, and 12-months in the medical record at follow-up visits (Appendix 2, Figure 1)

Suture and Operative Costs: We will record cost of suture for the posterior repair by calculating number of sutures used by the cost charged per suture. We will also calculate how much a procedure costs based on posterior repair operative time (cost/minute).

Anatomical and subjective surgical failure in posterior compartment: We will evaluate Stage of posterior prolapse on POP-Q examination, as well as with POPDI-6 portion of the PFDI-20 questionnaire. Standard definition of anatomical cure will be defined as Ba or Bp at </= 0 on POP-Q examination (i.e.at or beyond hymenal ring) and/or patient subjective symptom response on PFDI-20 questionnaire, with a negative response to questions: “Do you usually have a sensation of bulging or protrusion from the vaginal area?” and “Do you usually have a bulge or something falling out that you can see or feel in the vaginal area?” [21]

Adverse events: Any adverse event related to posterior repair or suture type will be reported. We will use the Modified Clavien-Dindo Classification System for surgical complications (Figure 3). We will also collect information from the EMR on if patients are re-admitted during the study time period (yes or no). Please refer to section on Adverse Events for details of reportable criteria.

Figure 3: Clavien-Dindo IV classification of complication

Grade	Description
I	Any deviation from the normal postoperative course without the need for pharmacologic treatment or surgical, endoscopic, and radiologic interventions
II	Requiring pharmacologic treatment with drugs other than such allowed for grade I complications (including blood transfusions and total parenteral nutrition)
III	Requiring surgical, endoscopic, or radiologic intervention
IIIa	Intervention not under general anesthesia
IIIb	Intervention under general anesthesia
IV	Life-threatening complication requiring intensive care unit management
V	Death of a patient

Modified Clavien classification of complications

STATISTACAL CONSIDERATIONS

Statistical Methods

The data will be analyzed as intent to treat. Descriptive statistics for all variables will be calculated by study group (intervention v. control). The primary analysis will compare VAS post-operatively at 6 weeks between study groups using Student's t test if normally distributed or the Wilcoxon rank sum test if not normally distributed. Secondary outcomes, demographics and other baseline variables will be compared between the two groups using the X^2 test or Fisher's exact test for categorical data, Student's t test for normally distributed data, and the Wilcoxon rank sum test for ordinal data or continuous data that are not normally distributed. Sensitivity analyses will be performed to assess how subjects who withdrew affect the results. SAS® Enterprise Guide 7.1 (SAS Institute, Cary, NC, USA) will be used for all analyses. All statistical tests will be two-tailed and a p-value of less than 0.05 will be considered statistically significant.

Sample Size Calculation

For our primary outcome we are utilizing the Visual Analog Scale (VAS) score at 6 weeks. Based on prior studies, a 33% change or a mean change of 20-30mm on a 100mm scale is needed to meet a threshold of clinical significance. [7, 21,23- 26] Crisp et al performed a randomized controlled trial evaluating pain after vaginal reconstructive surgery, assessing VAS at several time points.[21] For our sample size calculation, we used a VAS standard deviation estimate of 23.4mm, which is the largest standard deviation reported by Crisp et al. Group sample sizes of 23 and 23 are needed to achieve 80% power to reject the null hypothesis of equal means when the population mean difference is 20mm with a standard deviation of 23.4mm for both groups, with a significance level of 0.05 using a two-sided, two-sample, equal-variance t-test.

Missing data may occur if subjects fail to return for follow-up. However, since study subjects are undergoing surgery, they are more likely to return for their follow-up visits since most of these visits are part of their standardized postoperative care. Nevertheless, we will plan to account for a 15% drop-out rate, aiming to enroll 64 subjects with 32 in each group. Protocol amendment

was submitted to allow for enrollment of an additional 10 patients, for a total of 74 subjects, 36 per arm to allow for improved power given calculation based on a single study.

STUDY DOCUMENTATION AND MONITORING

Site Documentation

All study documents included in this protocol that will be presented to subjects will be submitted to the IRB for review. The Mercy site will maintain a study binder for all sites that will include the following:

- Enrollment log of patients that have consented to be in the study (electronic version)
- Protocol deviation log (electronic version)
- Adverse event log (electronic version)
- Investigator protocol and amendments
- IRB submissions, modifications, and renewals
- Data safety monitoring committee reports
- IRB approved consent form
- Data collection forms
- Patient assessment forms
- Patient questionnaires

Data Safety Monitoring

The research team will complete an initial report once 10% of the enrolled subjects have completed the 6 weeks outcome data collection; thereafter, a report will be completed every 6 months from the receipt of the DSMB's recommendations. This report will detail the progress and subject status, any adverse events, and any protocol deviation. The research coordinator will inform all study staff members of any unanticipated problems involving risks to study subjects or others. The research coordinator will facilitate and participate in internal monitoring visits by staff of the Office of Clinical and Translational Research at Atrium Health. This will include a thorough review of research subjects records, source documents, regulatory binders, and consent forms.

The Principal Investigator will monitor the study and assess the need for amendments as the study progresses. The PI will review the progress of each subject on the study and will apprise the IRB of adverse events or unexpected problems that may influence the IRB's decision to allow the trial to continue, in accordance with the IRB's standard operating procedures and policies. A protocol revision may be necessary for reasons including but not limited to rights, safety of subjects, welfare of subjects, and thus, an amendment will be required. Appropriate approvals (i.e., IRB) of the revised protocol must be obtained prior to implementation at each site.

The biostatistical team will generate periodic reports to monitor screening, enrollment, completeness of data for intervention implementation and outcomes, adverse events, and protocol deviations.

Data safety monitors will serve as an independent body to review the study data on a regular basis. The data safety monitors will include an external physician and an external research nurse. Data and safety monitoring responsibilities will consist of review of the research protocol and ongoing study activities, including review of data quality and completeness, review of fidelity to the study protocol, review of adequacy of subject recruitment and retention, review of adverse events, and making recommendations to the study PI and to the IRB concerning trial continuation, modification, or conclusion. Such monitoring helps to safeguard subject safety, ensure data quality, and provide ongoing training and support to ensure compliance. The data safety monitors will first convene to approve the study protocol and determine the frequency of meetings. After the first ten patients are enrolled and randomized, the study statisticians will generate a report for the data safety monitors to review. Content and frequency of the reports will be agreed upon prior to implementation of the trial. The PI will be responsible for ensuring that the study complies with the data safety monitors' requests.

Study Medical Device Information

Medical Risks related to delayed absorbable monofilament suture include but are not limited to the following: injury to surrounding structures, allergic reaction to suture material, surgical dehiscence of wound, wound infection, sutures remaining in place for extended periods (>6weeks) which may be associated with localized irritation, localized erythema or induration if suture placed superficially, failure to provide adequate wound support in closure of sites where expansion, stretching, or distension occurs, suture extrusion and delayed absorption in tissue with poor blood supply, poor cosmetic result, and/or broken needles may result in extended or additional surgeries or residual foreign bodies. Additionally, inadvertent needle sticks, may expose patient to bloodborne pathogens.

Protocol Deviations

Protocol deviations will be documented and logged on the Protocol Deviations log (electronic version). This will be done for every protocol related deviation related to any portion of the study timeline. Deviations will be reviewed and evaluated on an ongoing basis, and, as necessary, appropriate corrective and preventive actions (including notification, re-training, or discontinuation) will be put in place.

Data Safety Monitoring

Data safety monitors will include an external physician and research nurse. They will be tasked to review all adverse events that occur. A semi-annual report of all adverse events will be generated and sent to the data safety monitors every 6 months.

All Serious Adverse Events (SAEs) will be reported to the data safety monitors via email within 2 business days of site staff being informed of its occurrence. The PI and research nurse will be copied on all communications with the data safety monitors. Copies of de-identified source documentation regarding the SAE will be included, as well as other clinically meaningful documentation.

The PI (Dr. Amanda Merriman) will be responsible for ensuring that the study complies with the data safety monitors' requests.

Reporting Adverse Events

Adverse events (AE) will be recorded and reported per the criteria and timeline below.

All AEs must be recorded and entered into the AE log and REDCap. An event number will be assigned by each site and recorded. The DSMB will be tasked to review all adverse events that occur. A semi-annual report of all adverse events will be generated and sent to the DSMB every 6-months.

All Serious Adverse Events (SAEs) will be reported to the DSMB via email within 2 business days of site staff being informed of its occurrence. The PI and research nurse will be copied on all communications with the DSMB. Copies of de-identified source documentation regarding the SAE will be included, as well as other clinically meaningful documentation.

Reportable AEs include those determined to be related to the study medication. AEs not related to the study medications will not be collected. Please note that underlying diseases are not reportable AEs unless there is an increase in severity or frequency during the investigation. Death should not be recorded as an AE, but as an outcome of a specific SAE.

Any subject that suffers an allergic reaction to the study suture material will be unblinded. This will be a reported adverse event that will also be reported to the DSMB, as outlined above.

Adverse Event Definitions

Adverse Event: any untoward medical occurrence, unintended disease or injury, or any untoward clinical signs (including abnormal laboratory finding) in subjects, whether or not related to study medications

Serious Adverse Event: an adverse event that led to:

- Death
- Serious deterioration in the health of the subject that either resulted in
    - A life-threatening illness or injury
    - A permanent impairment of a body structure or a body function
    - Medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or body function

Unrelated: No evidence that the timing of the AE has a relationship to the time study medications were taken

Possibly Related: The AE has a timely relationship to the study medications, however a potential alternative etiology may be responsible for the AE

Probably Related: The AE has a timely relationship to the study medications and the causative relationship can clearly be established. No potential alternative etiology is apparent.

Severity Definitions

Mild: Awareness of signs or symptoms, but easily tolerated and are of minor irritant type causing no loss of time from normal activities. Symptoms do not require therapy or a medical evaluation; signs and symptoms are transient.

Moderate: Events introduce a low level of inconvenience or concern to the subject and may interfere with daily activities but are usually improved by simple therapeutic measures; moderate experiences may cause some interference with functioning.

Severe: Events interrupt the subjects' normal daily activities and generally require systemic drug therapy or other treatment; they are usually incapacitating.

Surgical complications
Surgical complications will be classified according to the Modified Clavien-Dindo Scale (I-V) (Figure 3).

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Additional resources to be added in manuscript:

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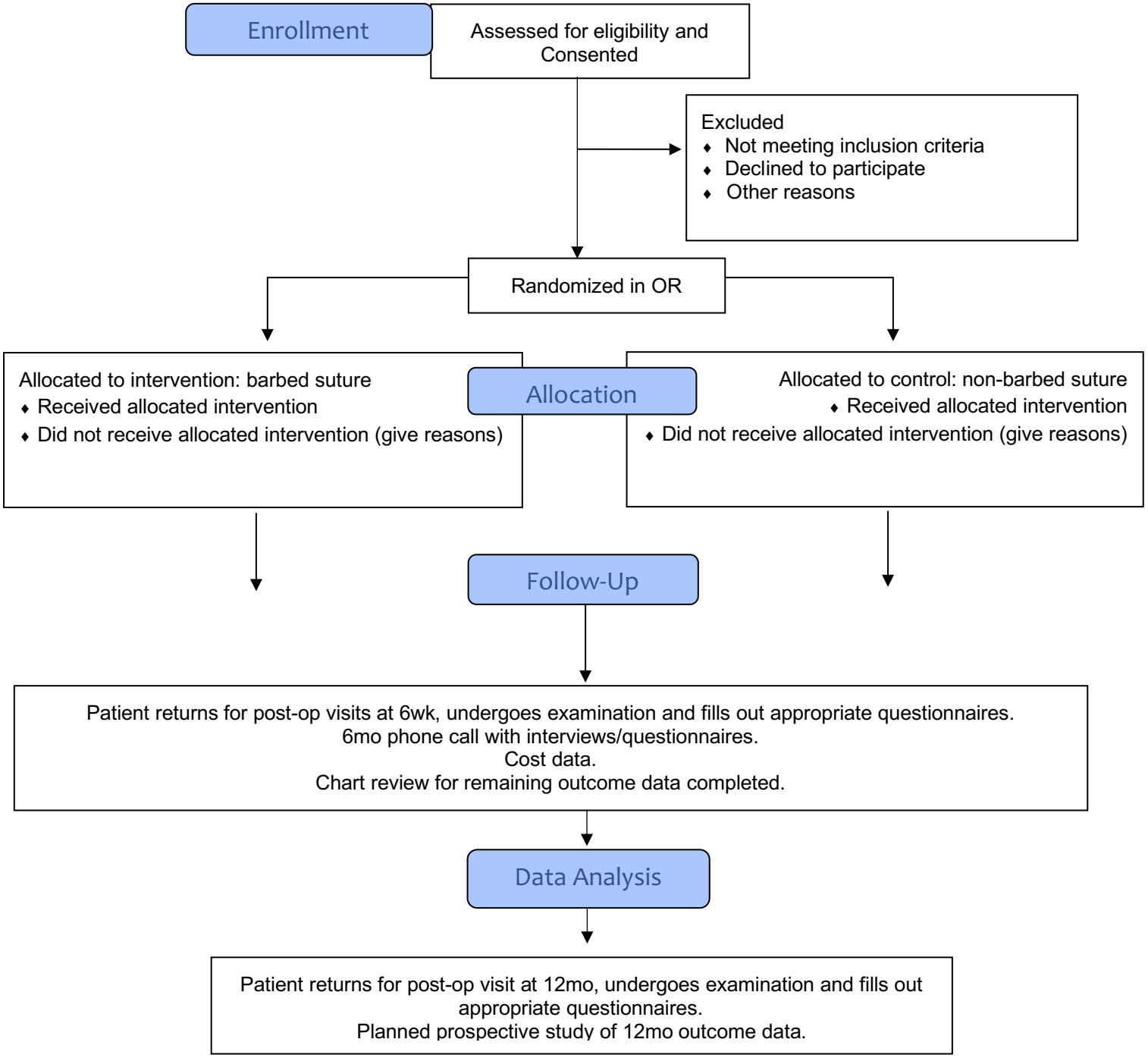
Appendix 1

FIGURE 1. Study Trial Consort Diagram



Appendix 2 (Questionnaires)

Figure 1. PFDI-20 example

Modified Pelvic Floor Distress Inventory-20

Patient ID#: _____ Date:_____

Pre-operative: ☐ Baseline

Post-operative: ☐ 6-weeks ☐ 6-months ☐ 12-months

Please answer each questions by checking the best response. While answering questions please consider your symptoms as an average over the past 1-month. We understand that you may not be experiencing a problem in all of these areas, but please answer to the best of your ability.

Colorectal-Anal Distress Inventory-8 (CRADI-8)

Do you experience, and, if so, how much are you bothered by...	No	Yes			
	0	Not at all 1	Somewhat 2	Moderately 3	Quite a bit 4
Feel you need to strain too hard to have a bowel movement?					
Feel you have not completely emptied your bowels at the end of a bowel movement					
Usually lose stool beyond your control if your stool is well formed?					
Usually lose stool beyond your control if your stool is loose?					
Usually lose gas from the rectum beyond your control?					
Do you usually have pain when you pass your stool?					
Experience a strong sense of urgency and have to rush to the bathroom to have a bowel movement?					
Does part of your bowel ever pass through the rectum and bulge outside during or after a bowel movement?					

Pelvic Organ Prolapse Distress Inventory- 6 (PFDI-6)

Do you experience, and, if so, how much are you bothered by...	No	Yes			
	0	Not at all 1	Somewhat 2	Moderately 3	Quite a bit 4
Usually experience pressure in the lower abdomen?					
Usually experience heaviness or dullness in the pelvic area?					
Usually have a bulge or something falling out of that you can see or feel in your vaginal area?					
Ever have to push on the vagina or around the rectum to have or complete a bowel movement?					
Usually experience a feeling of incomplete bladder emptying?					
Ever have to push up on the bulge in the vaginal area with your fingers to start or complete urination?					

Figure 2. PISQ-12 Pre-Operative/Post-operative Questionnaires

Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire (PSIQ-12)
Pre-Operative

Patient ID#: _____ Date:_____

The following are a list of questions about you and your partner's sex life pre-operatively. Your confidential answers will only be used to help doctors understand what is important to patients about their sex life. Please answer each questions by checking the best response. While answering questions, please consider your sexuality as an average over the past 6-months.

1. Are you sexually active (have you had sexual intercourse in the past 12-months?[1] If you answer **NO**, do not complete the remainder of the survey.

   ☐ Yes ☐ No

2. How frequently do you feel sexual desire? This feeling may include wanting to have sex, planning to have sex, feeling frustrated due to lack of sex, etc.

   ☐ Always ☐ Usually ☐ Sometimes ☐ Seldom ☐ Never

3. Do you climax (have an orgasm) when having sexual intercourse with your partner?

   ☐ Always ☐ Usually ☐ Sometimes ☐ Seldom ☐ Never

4. Do you feel sexually excited (turned on) when having sexual activity with your partner?

   ☐ Always ☐ Usually ☐ Sometimes ☐ Seldom ☐ Never

5. How satisfied are you with the variety of sexual activities in your current sex life?

   ☐ Always ☐ Usually ☐ Sometimes ☐ Seldom ☐ Never

6. Do you feel pain during sexual intercourse?

   ☐ Always ☐ Usually ☐ Sometimes ☐ Seldom ☐ Never

7. Are you incontinence of urine (leak urine) with sexual activity?

   ☐ Always ☐ Usually ☐ Sometimes ☐ Seldom ☐ Never

8. Does fear of incontinence (either stool or urine) restrict your sexual activity?

   ☐ Always ☐ Usually ☐ Sometimes ☐ Seldom ☐ Never

9. Do you avoid sexual intercourse because of bulging in the vagina (either the bladder, rectum or vagina falling out?

   ☐ Always ☐ Usually ☐ Sometimes ☐ Seldom ☐ Never

10. When you have sex with your partner, do you have negative emotional reactions, such as fear, disgust, shame or guilt?

    ☐ Always ☐ Usually ☐ Sometimes ☐ Seldom ☐ Never

11. Does your partner have a problem with erections that effects your sexual activity?

    ☐ Always ☐ Usually ☐ Sometimes ☐ Seldom ☐ Never

12. Does your partner have a problem with premature ejaculation that affects your sexual activity?

    ☐ Always ☐ Usually ☐ Sometimes ☐ Seldom ☐ Never

13. Compared to orgasms you have had in the past, how intense are the orgasms you have had in the past 3 months?

    ☐ Much less intense ☐ Less intense ☐ Same intensity ☐ More intense ☐ Much more intense

[1]Definition of sexual activity from National Institute on Aging (NIA).The National Social Life, Health and Ageing Project (NSHAP)

Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire (PSIQ-12)
Post-Operative

Patient ID#: _____ Date:_____

The following are a list of questions about you and your partner's sex life post-operatively. Your confidential answers will only be used to help doctors understand what is important to patients about their sex life. Please answer each questions by checking the best response. While answering questions, please consider your sexuality as an average over the past 6-months.

1. Have you had sexual intercourse since your surgery? If you answer **NO**, do not complete the remainder of the survey. ☐ Yes ☐ No

1. How frequently do you feel sexual desire? This feeling may include wanting to have sex, planning to have sex, feeling frustrated due to lack of sex, etc.

   ☐ Always ☐ Usually ☐ Sometimes ☐ Seldom ☐ Never

2. Do you climax (have an orgasm) when having sexual intercourse with your partner?

   ☐ Always ☐ Usually ☐ Sometimes ☐ Seldom ☐ Never

3. Do you feel sexually excited (turned on) when having sexual activity with your partner?

   ☐ Always ☐ Usually ☐ Sometimes ☐ Seldom ☐ Never

4. How satisfied are you with the variety of sexual activities in your current sex life?

   ☐ Always ☐ Usually ☐ Sometimes ☐ Seldom ☐ Never

5. Do you feel pain during sexual intercourse?

   ☐ Always ☐ Usually ☐ Sometimes ☐ Seldom ☐ Never

6. Are you incontinence of urine (leak urine) with sexual activity?

   ☐ Always ☐ Usually ☐ Sometimes ☐ Seldom ☐ Never

7. Does fear of incontinence (either stool or urine) restrict your sexual activity?

   ☐ Always ☐ Usually ☐ Sometimes ☐ Seldom ☐ Never

8. Do you avoid sexual intercourse because of bulging in the vagina (either the bladder, rectum or vagina falling out?

   ☐ Always ☐ Usually ☐ Sometimes ☐ Seldom ☐ Never

9. When you have sex with your partner, do you have negative emotional reactions, such as fear, disgust, shame or guilt?

   ☐ Always ☐ Usually ☐ Sometimes ☐ Seldom ☐ Never

10. Does your partner have a problem with erections that effects your sexual activity?

    ☐ Always ☐ Usually ☐ Sometimes ☐ Seldom ☐ Never

11. Does your partner have a problem with premature ejaculation that affects your sexual activity?

    ☐ Always ☐ Usually ☐ Sometimes ☐ Seldom ☐ Never

12. Compared to orgasms you have had in the past, how intense are the orgasms you have had in the past 3 months?

    ☐ Much less intense ☐ Less intense ☐ Same intensity ☐ More intense ☐ Much more intense

[1]Definition of sexual activity from National Institute on Aging (NIA).The National Social Life, Health and Aging Project (NSHAP)

Appendix 3

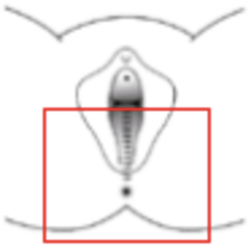
Figure 1: Patient Pain Assessment Forms (Pre-Operative/Post-Operative)

Patient Pain Assessment Form
Pre-operative

Patient ID#:_____ Date:_____

Instructions: Please answer the following questions to the best of your ability. These questions are meant to assess your baseline pain level prior to surgery.

1. In the past 1 weeks have you taken any pain medications (circle one): ☐ Yes ☐ No
2. If **yes** to question **1**, which pain medications:
   ☐ Ibuprofen ☐Tylenol ☐Percocet ☐Lortab ☐ Gabapentin ☐ other:_____
3. Are you taking a daily laxative or stool softener (circle one): ☐Yes ☐ No
4. If **yes** to question **3**, which laxative or stool softener: _____
5. If you have pain in the posterior vaginal compartment, please mark with one or multiple **X(s)** **within the RED BOX** on diagram where you feel the majority of your pain.



Instructions: Please consider your average pain in the posterior vaginal compartment over the past 1-week. Please place a single straight line in **BLUE INK** on the first line below to show your level of pain at rest (sitting or standing). On the second line, please draw another single straight line to show to show your level of pain with movement. See example below. Please use either a ruler or book to draw line.

EXAMPLE

Pain Level at Rest

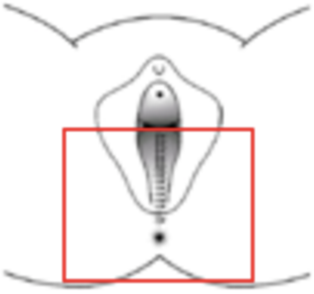
Pain Level with Movement

Patient Pain Assessment Form
Post-Operative

Patient ID#:_____ Date:_____

Instructions: Please answer the following questions to the best of your ability. These questions are meant to assess your pain level after surgery.

1. In the past 1 weeks have you taken any pain medications (circle one): ☐ Yes ☐ No
2. If **yes** to question **1**, which pain medications:
   ☐ Ibuprofen ☐Tylenol ☐Percocet ☐Lortab ☐ Gabapentin ☐ other:_____
3. Are you taking a daily laxative or stool softener (circle one): ☐Yes ☐ No
4. If **yes** to question **3**, which laxative or stool softener: _____
5. If you have pain in the posterior vaginal compartment, please mark with one or multiple **X(s)** **within the RED BOX** on diagram where you feel the majority of your pain.



Instructions: Please consider your average pain in the posterior vaginal compartment over the past 1-week. Please place a single straight line in **BLUE INK** on the first line below to show your level of pain at rest (sitting or standing). On the second line, please draw another single straight line to show to show your level of pain with movement. See example below. Please use either a ruler or book to draw line.

EXAMPLE

Pain Level at Rest

Pain Level with Movement

Appendix 4

Figure 1: Suture materials, A (PDS®), B (V-Loc™)

A

Characteristics	PDS II Suture
Material	Polydioxanone
Natural / Synthetic	Synthetic
Construction	Monofilament Absorbable
Coating	Not Coated
Color	Undyed Clear and Dyed Violet
Available Size Range	2 through 9/0 dyed 1 through 7/0 undyed
Strength Retention Profile	75% of original strength @ 2 weeks post-op 50% of original strength @ 4 weeks post-op 25% of original strength @ 6 weeks post-op
Absorption Time	Absorbed in 180 – 210 days
Absorption Process	Hydrolysis
Frequent Uses	Soft tissue approximation, including use in pediatric cardiovascular tissue where growth is expected to occur; ophthalmic surgery

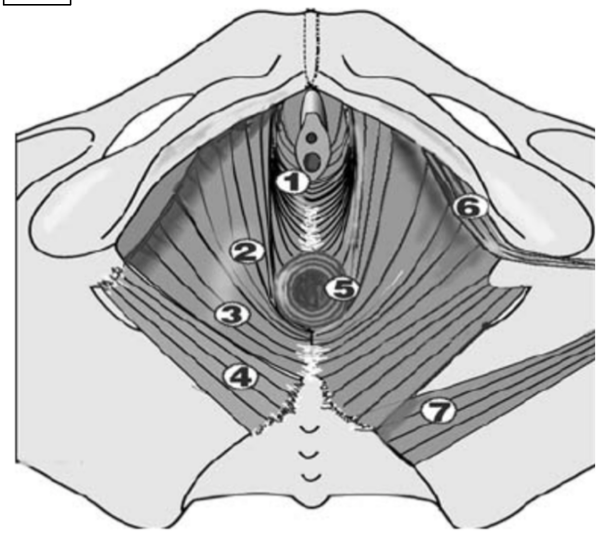
- At 42 days post-op, PDS II suture has more than twice as much strength as Maxon and Biosyn.
- Smooth easy passage through tissues.
- Less out-of-package memory than competition.
- Outstanding pliability in a monofilament suture.

B

	V-Loc™ 90 device	V-Loc™ 180 device
Tensile Strength	7 days, 90%; 14 days, 75%	7 days, 80%; 14 days, 75%; 21 days, 65%
Absorption Profile	90-110 days	180 days
Procedural Applications	Soft tissue approximation where support is required consistent with the absorption profile	Soft tissue approximation where support is required consistent with the absorption profile
Color	Undyed, violet 	Clear, green 
Composition	Glycolide, dioxanone and trimethylene carbonate	Copolymer of glycolic acid and trimethylene carbonate
Indications	V-Loc™ 90 device and V-Loc™ 180 absorbable wound closure devices are indicated for soft tissue approximation where use of an absorbable suture is appropriate.	

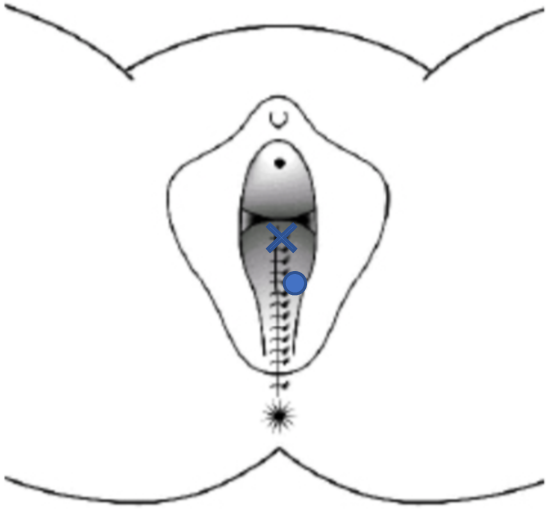
Figure 2: Example of Standardized Post-Op Exam Diagrams **A** (myofascial pain, systematic approach to examination),[27] **B** (anatomical view to mark suture burden), **C** (description of how to perform myofascial exam[28]

A



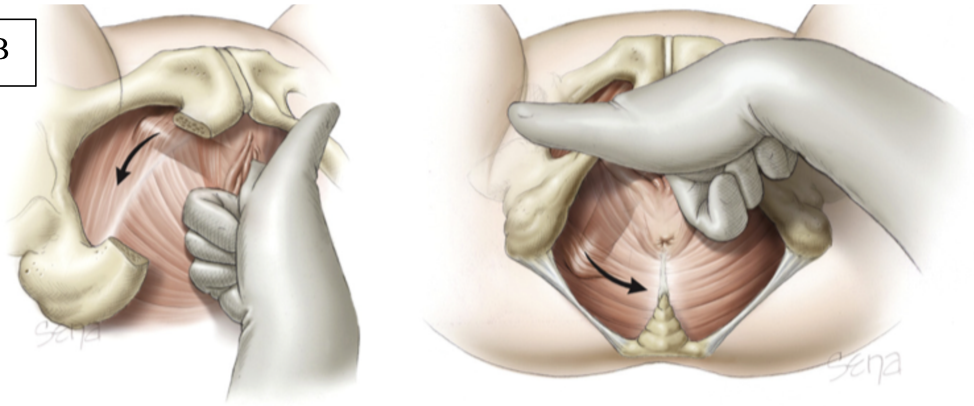
Common sites of trigger points in the pelvic floor. 1-Pubovaginalis, 2- puborectalis,3-iliococcygeus, 4-coccygeus, 5-analsphincter, 6-obturator internus, 7-piriformis

C



Mark with • where suture visualized; mark with **X** where suture palpated but not visualized. If able to visualize suture, describe if it is a knot that is visualized and what color the suture is **(green, purple, white, clear).**

B



Obturator Internus Levator Ani

Internal palpation is performed with the index finger of the dominant hand, once in the center of the muscle belly, then in a sweeping motion along the length of the muscle in the direction of the orientation of that muscle and proceeds counter-clockwise: right obturator internus (**A**), right levator ani (**B**), left levator ani, and then left obturator internus. Illustration used with permission of Ms Marie Sena.

Meister et al. Pelvic floor myofascial examination. Am J Obstet Gynecol 2019.