The Use of Anchor versus Suturing for Attachment of Vaginal Mesh in Minimally Invasive Sacrocolpopexy

12/8/17

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1. OBJECTIVES

1. **PRIMARY OBJECTIVE:** To assess the effect of absorbable anchor compared to suturing for mesh attachment to vagina in robotic assisted sacrocolopexy on the length of surgery for this portion of the procedure.
2. **SECONDARY OBJECTIVES:**
    i. To assess intraoperative and
    ii. postoperative complication rates,
    iii. Intraoperative 10 cm visual analog scale (VAS), to subjectively assess surgeon satisfaction with the technique
    iv. post-operative Pelvic Organ Prolapse Quantification (POPQ) evaluation for anatomic failure and
    v. a VAS of the vaginal walls overall appearance

2. HYPOTHESES For women undergoing sacrocolpopexy surgery at a large managed care organization:

1. **PRIMARY HYPOTHESIS:** Attachment of the mesh to the vagina with absorbable anchors compared to standard treatment (suturing) will require 50% shorter surgical time for the mesh attachment portion of the procedure.
2. **SECONDARY HYPOTHESIS:** Anchor suture staples compared to standard treatment will:
    i. have similar rates of intra-operative and post-operative complications
    ii. have similar rates of surgical failure
    iii. not have different appearance on the VAS of the vaginal walls
    iv. elicit higher reported satisfaction from surgeons

3. BACKGROUND

1. **PELVIC ORGAN PROLAPSE;** Pelvic organ prolapse (POP) is the descent of one or more of four different anatomic structures: a) the uterus (cervix), b) the apex of the vagina (in those status post-hysterectomy) c) the anterior vaginal wall, or d) the posterior vaginal wall. It is caused by chronic intra-abdominal pressure on weakened pelvic organ supports. An estimated 41.1% of women aged 50-79 have some degree of prolapse on exam [1,2], while only 2.9-8% of all adult women report symptomatic prolapse symptoms [3-5]. Severity of POP is defined by the Pelvic Organ Prolapse Quantification (POPQ) system [6]. Risk factors include age, childbirth (especially vaginal and operative vaginal deliveries), white race, family history, constipation, obesity, smoking, and menopause. Symptoms can include a vaginal bulge, pressure, or discomfort.
2. **SACROCOLPOPEXY:** Sacrocolpopexy (SCP) is a common surgical treatment for symptomatic pelvic organ prolapse. While traditionally reserved for women with recurrent or vaginal vault prolapse SCP is becoming more common as the first surgical option for women with prolapse [7], because benefits are long-lasting with less than 5% of patients undergoing reoperation [8-11] However, SCP is associated with an increased rate of intraoperative and post-operative complications compared to other surgical treatments [12], including bowel obstruction, mesh erosion, and venous thromboembolism. More recently minimally

invasive SCP (laparoscopic and robotic assisted) has become popular as it offers similar success rates with faster recovery, less pain, bleeding and cost [13-15]. Robotic surgery has several unique challenges including the absence of haptic feedback, and additional time required for setup. The mean time to complete robotic SCP is 79 minutes for attendings, and 76 minutes for trainees, with total operating time of 182 minutes for attendings, and 200 minutes for trainees [16].

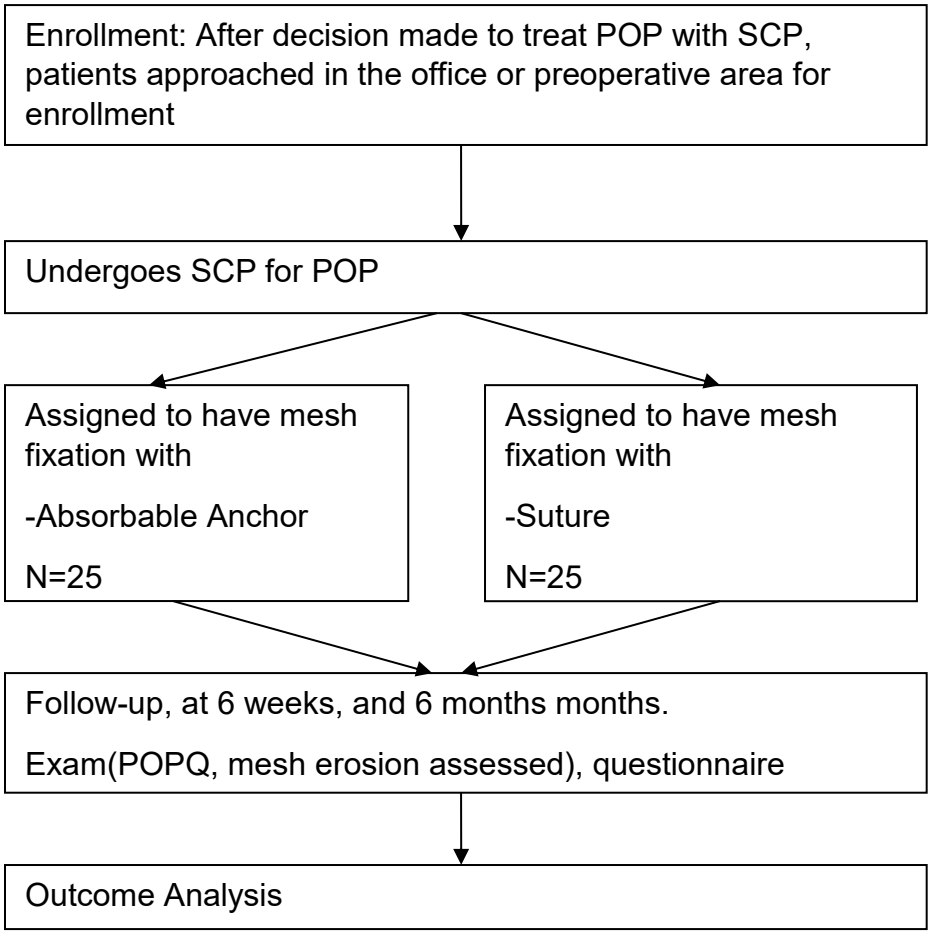
3. **ANCHOR MESH FIXATION:** Anchor mesh fixation has been tested successfully in several applications. In laparoscopic incisional and ventral hernia repair, anchors have been used to fixate mesh. A systematic review [17] found four trials involving 207 surgeries comparing traditional suture mesh fixation to anchoring. Anchoring was associated with shorter operative time, less postoperative pain and similar rates of perioperative complications and hernia recurrence and shorter hospital stay. Both non-absorbable (titanium helical anchors) and absorbable anchors (Absorboanchor™, Covidien; Sucerestrap™, Ethicon) have been used with similar operating time, postoperative hospital stay, pain, morbidity and recurrence [18-21]. However longer term studies have reported more pain and erosion of non-absorbable anchors into hollow viscera [22] but perhaps higher recurrence rates with absorbable anchors[23]. Comparison of acute fixation strength of various attachment techniques has been performed, finding suture to provide the greatest strength and non-absorbable to provide more strength then absorbable anchors [24]. However, it is well know that mesh used for vaginal attachment is incorporated into the tissue after three months and the use of absorbable sutures for mesh attachment for sacrocolpopexy are commonly used [25].
4. **PRIMARY OUTCOME MEASURE:** The primary outcome measure is mesh attachment time to the fibromuscular tissue layer in the vagina. In sacrocolpopexy done in a minimally invasive fashion, polypropylene mesh attachment to this layer of the vagina can be the most technically challenging and time intensive portion of the surgery. This is traditionally performed with non-barbed, delayed absorbable interrupted, suture (such as 2-0 PDS), with 4-6 interrupted sutures with 4 to 6 knots each on both the anterior and posterior aspect of the vagina. The anterior mesh attachment took 15 minutes, while posterior mesh attachment took 16 minutes on average [16] and the time to complete both took 42 minutes in another study[25]. The mesh attachment time has excellent validity as it directly measures the time it takes to complete the part of the surgery. With few exceptions, the measure of time has strong accuracy and precision due to the use of standardized procedures and consistent measurement technique.
5. **RATIONALE AND POTENTIAL SIGNIFICANCE OF RESULTS:** By applying a commonly used surgical technique of absorbable anchors to a new surgery, SCP, operative time may be decreased while providing similar patient outcomes. Absorbable anchors have been validated in mesh fixation during laparoscopic surgical repair of hernias. This

technique potentially takes less time than traditional suturing, thus decreasing cost and morbidity of anesthesia. Our hypothesis proposes that for women undergoing SCP at a large managed care organization, those receiving anchor suture staples to attach the mesh to the vagina compared to those receiving standard treatment will require 50% shorter surgical time for the mesh attachment portion of the surgery. Our secondary hypothesis is for women undergoing SCP at a large managed care organization, those receiving anchor suture staples to attach the mesh to the vagina compared to those receiving standard treatment will have similar rates of intra-operative and post-operative complications and surgical failure. On VAS, patients will not have different appearance of the vaginal walls. Surgeons will report higher satisfaction with the anchor technique.

4. OVERVIEW OF DESIGN

1. **DESIGN DESCRIPTION;** This is a multi-site prospective, randomized, single-blind, 2 arms-parallel, clinical trial to evaluate the effect of absorbable anchor versus suturing of polypropylene mesh to the vaginas fibromuscular layer on the length of procedure for women undergoing SCP for POP. This effect will be studied using timing of the surgical procedure.
2. The study consists of a 1-year enrollment period concurrent with a 1-year single blinded period (the intraoperative data in which the patient is blinded to group assignment, but the surgeon/investigator is not), followed by a 6-month postoperative double blinded period (in which both the patient and surgeon/investigator).
3. During enrollment, patients who meet the inclusion and not the exclusion criteria and provide informed consent for participation will be assigned randomly to receive either absorbable anchor mesh fixation or suture mesh fixation.

Figure 1. Flowchart of study schema



4. **SCREENING PERIOD:** Subject will be screened for eligibility during a 1-year period that will include the preoperative office visit and preoperative unit visit. Office staff (research nurses, nurse practitioners, residents, fellows, attendings) will obtain written informed consent from participants as a part of enrollment. Standard physical exam measures (including POPQ) will be performed during the office visit. The suture allocation sealed envelope will be opened intra-operatively once it is certain the attachment of mesh will occur via a technique that is minimally invassive.
5. **STUDY PERIOD:** Study duration will be the 1 year concurrent period where surgeries are performed as well as the subsequent 6 months where postoperative visits occur. After randomization and surgery occurs subjects will follow up for a total of 6 months, with three visits, one at 6 weeks, one at 6 months. During these postoperative visits, a standard physical exam will be performed looking for signs of POP recurrence, mesh erosion, palpable suture, anchors, and other physical findings. The

patient will complete standardized questionnaires accessing pain, satisfaction and other quality of life indicators.

6. **STUDY POPULATION:** Women with POP, scheduled for minimally invasive SCP will be eligible for enrollment
    i. **INCLUSION CRITERIA:** All patients must meet all the following inclusion criteria.
        1. Age 21 or older
        2. Diagnosis of POP, defined as the descent of one or more of four different anatomic structures, a)the uterus(cervix), b)the apex of the vagina (in those status post hysterectomy) c) the anterior vaginal wall, or d) the posterior vaginal wall. This is defined on exam as the POPQ points Ba, C, or Bp >0 cm beyond the hymen, uterine(cervix) descent into at least the lower half the vagina (defined as point c> -tvl/2) or post hysterectomy vault into the lower 2/3 of the vagina. Bothersome bulge symptoms as indicated on question 3 of the Pelvic Floor Disorder Inventory (PFDI-20) form relating to 'sensation of bulging' or something 'falling out'
        3. Desire surgical treatment for POP with SCP
        4. Available for up to 6 months of follow up
        5. Not pregnant or desiring future pregnancy
        6. Written informed consent is obtained.
    ii. **EXCLUSION CRITERIA;** Patients are ineligible for the study if:
        1. Known adverse reaction to synthetic mesh, or complications including but not limited to erosion, fistula, or abscess.
        2. Cervical intraepithelial neoplasia (CIN2, CIN3, or cancer)
        3. Unresolved chronic pelvic pain
        4. Prior abdominal or pelvic radiation
        5. Contraindications to the surgical procedures including known horseshoe kidney, pelvic abscess or active diverticular abscess or diverticulitis
7. **METHODS OF RECRUITMENT AND MULTIPLE STRATEGY OF RETENTION:** There are many women in the target population. We will educate the health personnel (research nurses, nurse practitioners residents, fellows, attendings) in two sites of a large managed care organization Female Pelvic Medicine and Reconstructive Surgery (FPMRS) to recruit this population. Subject retention strategies will include a $20 visa gift card given to the subject on completing the 6 month follow up appointment, as well as phone call reminders of those appointment.

5. **STUDY PROCEDURES**
    1. **INTERVENTION:** On day of surgery eligible individuals are randomized to have either absorbable anchor or suture fixation of mesh (Figure 1). The patients and all postoperative study staff will be blinded to treatment assignment and surgical time measurements. A block stratification with a computer-generated randomization schedule will be performed. Equipment needed for both techniques will be stocked and readily

available and all surgeons will be trained in the use of both techniques. The two groups will be mesh attachment with 0 non-barbed delayed absorbable suture or anchor suture using the Reliatack™ articulating reloadable fixation device (Medtronic). A minimum number of suture attachment points will be 4 on each side of the vagina. The average number for most cases is typically 6 to 8 per side. The same number minimum number of anchors will be required for the anchor arm. The remaining portion of the procedures will be the same for both arms. Intra-operative details will be tracked including number of sutures/anchors placed per side, inability to complete anchor placement or suture placement and alternative method if needed, and anchor or suture exposure full thickness in the vagina, and insertion of anchor/suture in rectum or bladder requiring removal. The type of suture will not be revealed in the operative procedure or heading but will be described in the description of procedure. Perioperative antibiotics will be administered per operating room protocol. Patients will all be prescribed vaginal estrogen after surgery.

2. **ASSESSMENTS**
    i. **STUDY SCHEDULE**

The timing of study is summarized in the Study Schedule.

	Screening	Surgery	Post-Operative Visits	
Visit	1	1	1	2
Month	Pre-op	0	1.5	6
Informed consent	X			
Demographics	X			
Pregnancy	X			
Efficacy				
POPQ	X		X	X
Procedure length		X		
Surgeon+Fellow Satisfaction (VAS)		X		
PGI-I			X	X

PFDI 20	X			
Safety				
Vaginal Wall Appearance (VAS)			X	X
Adverse events		X	X	X
Patient VAS for Pain			X	X

ii. **POP DIAGNOSIS/BASELINE POPQ:** During the preoperative visit for evaluation of POP, the provider (nurse practitioner, resident, fellow, and/or attending) will perform a POPQ exam. Each component, Aa(midline anterior vaginal wall, 3cm above external urethral meatus), Ba(most distal point of the anterior vaginal wall from the vaginal cuff or cervix, C(most distal edge of the cervix or cuff), GH(the distance from the middle of the external urethral meatus to posterior hymen), PB(posterior margin of the genital hiatus to midanal opening), tvl(greatest depth of the vagina, Ap(midline posterior vaginal wall, 3cm proximal to the hymen), Bp(the most distal point of the posterior vaginal wall from the vaginal cuff or cervix), D(posterior fornix) will be assessed. Patient will be diagnosed with POP, defined as the descent of one or more of four different anatomic structures, a) the uterus(cervix), b)the apex of the vagina (in those status post hysterectomy) c) the anterior vaginal wall, or d) the posterior vaginal wall. This is defined on exam as the POPQ points Ba, C, or Bp >0 cm beyond the hymen. In addition, uterine (Cervix) descent into at least the lower half of the vagina (defined as point C>-TVL/2) or post hysterectomy vault into the lower 2/3 of the vagina, Bothersome bulge symptoms as indicated on question 3 of the PFDI-20 form relating to ‘sensation of bulging’ or ‘something falling out,’ and desires surgical treatment for uterovaginal or vault prolapse undergoing minimally invasive SCP.

iii. **BASELINE DEMOGRAPHICS:** Patient baseline demographic information will be assessed from the electronic medical record. Information on age, BMI, ethnicity, co-morbidities, and allergies will be obtained.

iv. **INTRAOPERATIVE:** The following will be tracked: intraoperative adverse events, total surgical time, sacrocolpopexy time, mesh attachment time, type of mesh, number of attachment points

(anchor or mesh) including total, anterior, posterior, inability to use randomized technique, conversion to open or alternative technique, surgeon satisfaction with method.

v. **IMMEDIDIATE POSTOPERATIVE:** Length of stay in hours, pain medication use will be assessed.

vi. **POSTOPERATIVE CLINIC VISITS:** In addition to the preoperative visit, patients will have data collection intraoperatively and during postoperative visits at 6 weeks, and 6 months. We will mask patients to the type of attachment used until after their 6 month visit. A provider (not the who did the surgery) will do the postoperative POPQ measurements to ensure masking to the attachment technique used during surgery.

vii. **SAFETY ASSESSMENTS:** Safety is assessed as a component of the intraoperative record as well as a review of 6 months of electronic medical record of unscheduled office or emergency room visits in addition to assessments at the 6 week and 6 month postoperative visit.

3. **OUTCOMES**

i. **PRIMARY OUTCOME MEASURE:** The primary efficacy outcome is the mesh to vagina attachment time using these two techniques. The timing of the mesh attachment interval was defined as beginning at the time of the initial needle or anchor being loaded on the needle driver or anchor device within the body of the patient and was introduced into the tissue of the vagina to attach the piece of mesh. As long as minimum amounts are met, here is no boundary to the amount of passes used or the amount of sutures applied. The security of the attachment of mesh will be ascertained by the attending surgeon's clinical reasoning. The time interval will end at the time the final suture is detached or anchor placed. A recording of the suture quantity utilized for each mesh attachment interval and the quantity of sutures placed in order to attach the mesh will be done. As this a time consuming component of sacrocolpopexy, a reduction in time using the anchor technique would be of considerable interest. This Mesh Attachment Interval will be recorded along with occurrence of supracervical hysterectomy as well as number of sutures or anchors placed, technical difficulties experiences, and mesh type on a de-identified document for each subject

1. **Validation of primary outcome (timing surgical procedures):** Measurement of time to complete a component of surgery has been validated in the surgical literature[16,25].
2. **Randomization/Blinding:** While intraoperative outcomes are not blinded, the examining postoperative visit provider will be blinded to group allocation. Group assignment will be performed by randomization as above.

ii. **SECONDARY OUTCOME MEASURE:** Our secondary efficacy objectives include: 1) VAS of the operating surgeon subjective technique satisfaction assessment 2) post-operative POPQ, mesh erosion anatomic assessment, palpable anchor assessment and 3) VAS of the vaginal walls general appearance. The latter two will be recorded by the provider who is blinded at 6 weeks and 6 months, who will perform POP-Q as well as the VAS assessment of the walls of the vagina's general appearance. Surgical failure of a patient is if the points on POP-Q, if Bp, Ba ≥ 0 cm, or C > - ½ TVL. The VAS will have four components, global satisfaction, apex, anterior wall, and posterior wall. The instructions for all four VAS will be as follows: "Please designate a "X" at the VAS that rates closest your sacrocolpopexy evaluation." The anterior compartment assessment at the VAS left side will say " the vaginal mesh at the ANTERIOR seems to lay level without folding or bunching." At the other VAS side the text will say "mesh at the vaginal ANTERIOR is completely folded and bunched." Comparable phrasing will be used on the for posterior and apical compartment VAS. For the global satisfaction VAS, the side on the left it will say "I will use this suture routinely; as it meets my needs for attachment of mesh" and text at the other VAS end will say "I do appreciate the results, I will not use this attachment technique in my practice;".

iii. **SAFETY AND TOXICITY MEASURES:** Safety will be assessed as several points throughout the study. During the admission for surgical care, safety measures and complications will be assessed. During the surgery and admission, complications, including but not limited to hemorrhage, bleeding, nerve injury, infection, urinary retention, bowel injury, bladder/urethral injury will be assessed. Post-operatively at the 6 week, and month visit (along with query of electronic medical record for additional ER and ambulatory visits) additional safety measures will be assessed. At the standardized postoperative visits mesh exposure and erosion will be assessed. In addition pain and reoperation for pain or mesh erosion and exposure will be assessed.

4. **MONITORING AND ETHICAL CONSIDERATIONS:** To safeguard complete, reliable and accurate data, the principal investigator will:
   i. provide preliminary and follow up training to study coordinators and providers on research procedure, participant recruitment, and completion of outcome reports
   ii. work with the IRB to obtain approval of the study and the informed consent document before the study can begin. A study role list will be created to include all qualified persons to whom the investigator may delegate study-related duties
   iii. Periodically evaluate outcome reports for correctness and missing values as well as keep a research database for the same and to ensure compliance with the IRB

iv. be continuously available to back the research staff by email, and telephone
v. conduct quality review of the database
vi. supervise that once entered, subject data will be accessed only for two purposes, analysis and validation/verification/auditing.

6. DATA MANAGEMENT AND ANALYSIS

1. PROCEDURES FOR DATA COLLECTION: Study participants will be closely observed by investigators to make sure that surgical appointments are set up. Data from preoperative period will be taken from the the EMR for the subject. Data for the primary outcome will be abstracted when the subject has their surgery.
   A Clinical report Form (CRF) will be used to collect history, physical examination, operation, operating times, technique, mesh attachment interval times, complications, and subsequent follow-up examination data. The investigators will input data into a pre-formatted spreadsheet. The spreadsheet will be maintained through the Kaiser Permanente San Diego research department on a password protected server and will be audited, reviewed and maintained by the investigators
   i. Quality of Data: Data of the highest quality will be obtained from management data defined protocols for evaluating its accuracy (using source verification), completeness, accountability, and integrity.
   ii. Completeness: the investigators will identify and complete any missing data.
   iii. Accuracy: Errors in data will likely stem from errors in data entry. To minimize this, confirmation of data with a second source and random checks of data, and will be done. Error catching mechanisms in the Excel spread sheet and Access Database will be created with appropriate ranges and limits to help catch mistakes in data entry and allow for more accurate data entry.
   iv. Auditing: Both sample and schedule-based auditing will be performed. Quarterly audits will be performed with random selection of 10% of the data to verify. Administrative audits will be done on a similar schedule to ensure compliance with Good Clinical Practices of the FDA.
   v. Accountability: Accountability for data entry and data management will be with the investigators and statistical consultants.
   vi. Integrity: mirrored hard drives, data back ups and storage on Kaiser Permanente San Diego server, will insure for data integrity.
2. ANALYSIS OF BASELINE DATA: Subject characteristics (measures and demographic information) collected at baseline will be compared across treatment groups, using either chi-square for categorical variables or t-test for continuous variables. We will examine these baseline characteristics for statistically significant differences between treatment groups, and use those that are identified for adjusted analysis correcting for these

differences in analysis of outcome variables.

3. STATISTICAL ANALYSIS OF OUTCOMES: The primary endpoint for this study is the time of completion of mesh attachment. Statistical methods will include t-test or Mann Whitney U test for continuous variables, and chi-squared or Fischer's exact-test for categorical variables. We will collect the primary measure for outcomes of time of mesh attachment as a continuous variable. In addition we will use t-tests to evaluate the mean times of the different attachment approaches. Paired sample t test will be used to evaluate POP-Q values pre and postoperatively. Chi-squared test will be used to examine anatomic failures between the two. We will do risk analysis as appropriate using 95% confidence intervals odds ratios. For the analysis we will use SPSS 22.0.
4. STUDY POWER AND SAMPLE SIZE: A time of mesh attachment power calculation was performed using Power and Sample Size program (PS version 3.1.2). If suture mesh attachment interval = 40 ± 20 mins [16,25], a 50% reduction with use of anchors is = 20mins ± 20 mins. With 80% power and αlpha=0.05, 17 subjects will be needed for each arm. Anticipating a drop out of up to a 30% we will enroll 25 subjects in each group for a goal of at least 17 participants for each arm.

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