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

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1. STATISTICAL 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.