

## RESEARCH PROTOCOL

Protocol Title:	<b><u>A randomized, controlled trial after vaginal apex suspension comparing force of stream to traditional retrograde fill voiding trial</u></b>
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IRB Number:	

### Guidelines for Preparing a Research Protocol

#### Instructions:

- You do not need to complete this document if you are submitting an *Application for Exemption* or *Application for a Chart Review*.
- Do not use this template if:
  - Your study involves an FDA regulated product. In this case, use the *Clinical Trial Protocol Template*.
  - Your study has a protocol from a sponsor or cooperative group. In this case, use the *Protocol Plus*.
  - Your study is a registry or repository for data and/or samples, In this case, use *Protocol Template – Registry Studies*.
- If a section of this protocol is not applicable, please indicate such.
- Do not delete any of the text contained within this document.
- Please make sure to keep an electronic copy of this document. You will need to use it, if you make modifications in the future.
- Start by entering study information into the table above, according to these rules:
  - Protocol Title: Include the full protocol title as listed on the application.
  - Investigator: include the principal investigator’s name as listed on the application form
  - Date Revised: Indicate the date at which the protocol was last revised
  - IRB Number: Indicate the assigned IRB number, when known. At initial submission, this row will be left blank.
- Once the table information is entered, proceed to page 2 and complete the rest of the form.

↓ Continue to next page to begin entering information about this study ↓



## 1. PREVIOUS STUDY HISTORY

Has this study ever been reviewed and rejected/disapproved by another IRB prior to submission to this IRB?

No  Yes – if yes, please explain:

## 2. BRIEF SUMMARY OF RESEARCH

- *The summary should be written in language intelligible to a moderately educated, non-scientific layperson.*
- *It should contain a clear statement of the rationale and hypothesis of your study, a concise description of the methodology, with an emphasis on what will happen to the subjects, and a discussion of the results.*
- *This section should be ½ page*

It is common to have voiding difficulties after prolapse and incontinence surgeries. Difficulties in voiding are seen in up to 47% of patients after transvaginal prolapse surgery in the immediate hours postoperatively<sup>6</sup>. Accepted protocols for voiding trials after prolapse and incontinence surgeries do not exist. Traditionally, many surgeons measure postvoid residual (PVR) urine volume to assess incomplete bladder emptying by retrograde filling of the bladder with a predetermined amount of normal saline or water. The catheter is then removed and the patient is permitted to void into a collection basin. The amount in the basin is subtracted from the filled amount. The need for postoperative catheterization is generally based on arbitrarily determined ratios of voided urine to PVR. The force of stream trial (FAST) does not prioritize amount voided, but rather the patient's subjective force of stream. Using FAST, a patient uses a VAS scale to quantify her force of stream. If she states that her Force of Stream (FOS) is >50% of her baseline prior to surgery, independent of the amount voided, she is discharged without a catheter. If the FOS is <50%, a PVR is measured via bladder scan. If her PVR is <500cc the patient is discharged home.

No randomized control trials (RCT) have been performed comparing the FAST method to the traditional retrograde voiding trial in subjects undergoing vaginal apex prolapse surgery despite the promising findings that FAST voiding trials are as reliable and safe as retrograde voiding trials in patients undergoing anti-incontinence surgeries. Standard in our practice is to perform a voiding trial on postoperative day 1 on all patients after vaginal apical prolapse surgery if they are to be discharged without a catheter. We would like to compare the FAST voiding trial to a traditional retrograde voiding trial with respect to the rate of catheterization among those discharged without a catheter within the six-week postoperative period in patients undergoing a vaginal apex prolapse surgery. We hypothesize the FAST voiding trial method is not inferior to traditional retrograde voiding trial. Subjects will complete questionnaires to examine postoperative bladder function, symptom distress and quality of life before and after surgery during their routine postoperative visits. We anticipate to find no difference in rates of catheterization in those discharged without a catheter in the 6-week postoperative period, the rate of urinary tract infection, the number of emergency room or unplanned office visits for voiding dysfunction or urinary tract infections, or a difference in urinary symptom scores using the questionnaires.

### 3. INTRODUCTION/BACKGROUND MATERIAL/PRELIMINARY STUDIES AND SIGNIFICANCE

- *Describe and provide the results of previous work by yourself or others, including animal studies, laboratory studies, pilot studies, pre-clinical and/or clinical studies involving the compound or device to be studied.*
- *Include information as to why you are conducting the study and how the study differs from what has been previously researched, including what the knowledge gaps are.*
- *Describe the importance of the knowledge expected to result*

The acceptable amount voided urine during the traditional retrograde voiding trial varies among practitioners. In a study by Kleeman et al, the patient was required to void >50% of volume filled during retrograde fill for discharge from hospital without an indwelling Foley catheter<sup>7</sup>. Pulvino et al, required that the patient void > 2/3 the amount of the volume placed during retrograde fill<sup>8</sup>. The force of stream trial (FAST) does not prioritize amount voided, but rather the patient's subjective force of stream.

A double-blinded randomized trial was performed to compare retrograde bladder filling versus FAST in 108 patients undergoing outpatient midurethral sling surgery<sup>10</sup>. Authors defined passing the retrograde filling test with voiding at least two-thirds of the instilled amount whereas passing the FAST method required the subject to disclose a FOS at least 50% of the baseline regardless of the volume voided. No differences were found between incidence of catheterization between the two groups (retrograde 25.5%, force of stress 26%; p=0.95) and no differences in urinary symptom and distress scores and pain scores on questionnaires given postoperatively. Importantly, no patients who passed either the FOS or retrograde fill tests required catheter reinsertion within 6 weeks postoperatively. The authors concluded the FAST test is a reliable and safe method of testing for voiding dysfunction after midurethral sling surgery.

Temporary catheterization does not pose a significant medical risk, but it is perceived as an inconvenience, a source of discomfort, and may be distressing for many patients. Elkadry et al. evaluated patient perception on surgical outcomes and concluded that 9% of women believed postoperative catheterization to be a surgical complication<sup>12</sup>. In addition to the distress and incontinence a catheter poses on a patient, resources and time must be spent in teaching proper care of an indwelling Foley catheter by nursing or housestaff.

No randomized control trials (RCT) have been performed comparing the FAST method to the traditional retrograde voiding trial in subjects undergoing vaginal apex prolapse surgery despite the promising findings that FAST voiding trials are as reliable and safe as retrograde voiding trials in patients undergoing anti-incontinence surgeries.

### 4. OBJECTIVE(S)/SPECIFIC AIMS AND HYPOTHESES

- *A concise statement of the goal(s) of the current study.*
- *The rationale for and specific objectives of the study.*
- *The goals and the hypothesis to be tested should be stated.*

We would like to compare the FAST voiding trial to a traditional retrograde voiding trial with respect to the rate of catheterization among those discharged without a catheter within the six-week postoperative period in patients undergoing a vaginal apex suspension surgery. In addition we aim to identify the number of patients sent home with a catheter due to failure of their respective voiding trial, the rate of reported urinary tract infections, the rate of unexpected or emergent visits for voiding dysfunction or urinary infections, the time from passing the voiding trial to catheterization within the 6-week postoperative period, and the degree of urinary symptoms and impact on quality of life in the postoperative period.

## 5. RESOURCES AVAILABLE TO CONDUCT THE HUMAN RESEARCH

- *Explain the feasibility of meeting recruitment goals of this project and demonstrate a potential for recruiting the required number of suitable subjects within the agreed recruitment period*
  - *How many potential subjects do you have access to?*
- *Describe your process to ensure that all persons assisting with the trial are adequately informed about the protocol and their trial related duties and functions*

Our division performs approximately 200 vaginal apex suspension surgeries for pelvic organ prolapse in a 12-month period. It is standard of care in our practice that all patients after vaginal apical prolapse surgery must complete a voiding trial on postoperative day 1 if they are to be discharged without a catheter. We assess postoperative voiding function using the traditional retrograde fill with 300cc saline or water postoperative day 1 prior to discharge. We also require a 2/3 quantity voided for discontinuation of catheter. The availability of potential subjects who meet eligibility criteria for this study is adequate for completion in 12 month period. All co-investigators are fellows or attending faculty in the division of urogynecology who are able to screen and approach subjects for enrollment. All are well versed in voiding trial management and protocol adherence.

## 6. RECRUITMENT METHODS

- *Describe the source of potential subjects*
- *Describe the methods that will be used to identify potential subjects*
- *Describe any materials that will be used to recruit subjects. A copy of any advertisements (flyers, radio scripts, etc.) should be submitted along with the protocol.*
- *If monetary compensation is to be offered, this should be indicated in the protocol*

The study population will be patients of the Urogynecology practice of Northwell Health System who are scheduled for surgery for vaginal apical prolapse with or without concomitant midurethral sling, anterior or posterior colporrhaphy. Patients will be randomized to one of two methods of voiding trial. Randomization will be stratified by site of surgery (Long Island Jewish Hospital or North Shore University Hospital) as well as type of surgery (apical vaginal prolapse surgery with a sling or apical vaginal prolapse surgery without a sling). All subjects over 18 years of age will be screened for eligibility relative to the patient inclusion and exclusion criteria. Recruitment for the study will be done via direct contact from our patient population. If a subject is found to be eligible to participate, an approved study investigator will approach her during her scheduled preoperative visit or in the hospital prior to her surgery. No form of advertisement will be used. The recruitment methods used will provide equitable selection of subjects. No forms of monetary compensation will be provided. Patients who are scheduled to have a surgery for vaginal apical prolapse with or without midurethral sling and with or without anterior and/or posterior colporrhaphy will be approached for study enrollment. Surgical procedures intended for treatment of vaginal apical prolapse are: uterosacral vaginal vault suspension, abdominal sacral colpopexy, colpocleisis, and sacrospinous ligament fixation. After informed consent is obtained, patients will be asked to complete the Urinary Distress Inventory (UDI-6), American Urological Association Symptom Score (AUASS) at the time of consent. The patient will be randomized to the FAST or traditional retrograde fill voiding trial.

## 7. ELIGIBILITY CRITERIA

- *Describe the characteristics of the subject population, including their anticipated number, age, ranges, sex, ethnic background, and health status. Identify the criteria for inclusion or exclusion of any subpopulation.*
- *Explain the rationale for the involvement of special classes of subjects, such as fetuses, pregnant women, children, prisoners or other institutionalized individuals, or others who are likely to be vulnerable. You cannot include these populations in your research, unless you indicate such in the protocol*
- *Similarly, detail exclusionary criteria: age limits, special populations (minors, pregnant women, decisionally impaired), use of concomitant medications, subjects with other diseases, severity of illness, etc.*

All subjects over 18 years of age will be screened for eligibility relative to the patient inclusion and exclusion criteria. Our subject population comprises of women, ages range 18-95, various stages of physical health, who suffer from pelvic organ prolapse. The subjects have chosen, in consultation with their physician, to undergo surgery to correct their pelvic organ prolapse. It is standard of care in our practice for patients to have a medical evaluation and clearance by their internist prior to surgery to determine if patient is safe to undergo surgery. Subjects will be excluded if any of the following apply:

1. Patients who underwent a surgery that requires long term catheterization (i.e fistula repair or urethral diverticulum)
2. Patients who sustained a cystotomy during surgery as our divisional protocol is to send these patients home with a Foley catheter for 5-14 days without a voiding trial
3. Patients with baseline urinary retention and the inability to urinate without catheterization
4. Pregnant women

## 8. NUMBER OF SUBJECTS

- *Indicate the total number of subjects to be accrued locally. If applicable, distinguish between the number of subjects who are expected to be pre-screened, enrolled (consent obtained), randomized and complete the research procedures.*
- *If your study includes different cohorts, include the total number of subjects in each cohort.*
- *If this is multisite study, include total number of subjects across all sites.*

The proposed sample size for this one year study is a total of 154 evaluable subjects (n=77 randomized to each voiding group). A subject will be “evaluable” if she gets randomized and is able to undergo the voiding trial. A subject who is not able to undergo the voiding trial is considered “not evaluable” and would not be included in the analysis.

## 9. STUDY TIMELINES

- *Describe the duration of an individuals participation in the study*
- *Describe the duration anticipated to enroll all study subjects*
- *The estimated date of study completion*

This study will be conducted over 12-month period. Given our availability of potential subjects in our practice, enrollment will be completed in a timely fashion.

## 10. ENDPOINTS

- *Describe the primary and secondary study endpoints*
- *Describe any primary or secondary safety endpoints*

### **Primary:**

The primary outcome variable of interest is the rate of catheterization within the six-week post-operative period following surgical repair of POP, among those discharged without a urinary catheter.

### **Secondary:**

1. Proportion of patients discharged with a catheter (this is essentially the proportion of patients who failed the voiding trial)
2. Proportion of patients who reported *any* UTI within the six-week post-operative period. The number of UTIs reported by each patient during that period will also be recorded.
3. Proportion of patients with emergency room visits or unexpected visits to the Urogynecology clinic for voiding dysfunction or suspected infection, within the six-week post-operative period. The number of ER visits or unexpected clinic visits will also be recorded.
4. Time-to-catheterization post-discharge: This is the number of days from discharge to catheterization (within the 6-week period post-surgery). Subjects who are not catheterized by the end of the follow-up period will be considered 'censored'.
5. Patient satisfaction with postoperative bladder function (measured at baseline, 2-weeks post-op and 6 weeks post-op) using:
  - a. American Urological Association Symptom Score (AUASS)
  - b. Urinary Distress Inventory (UDI-6)

## 11. RESEARCH PROCEDURES

- *Include a detailed description of all procedures to be performed on the research subject and the schedule for each procedure.*
- *Include any screening procedures for eligibility and/or baseline diagnostic tests*
- *Include procedures being performed to monitor subjects for safety or minimize risks*
- *Include information about drug washout periods*
- *If drugs or biologics are being administered provide information on dosing and route of administration*
- *Clearly indicate which procedures are only being conducted for research purposes.*
- *If any specimens will be used for this research, explain whether they are being collected specifically for research purposes.*
- *Describe any source records that will be used to collect data about subjects*

- *Indicate the data to be collected, including long term follow-up*

Patients who are scheduled to have a surgery for vaginal apical prolapse with or without midurethral sling and with or without anterior and/or posterior colporrhaphy will be approached for study enrollment. Surgical procedures intended for treatment of vaginal apical prolapse are: uterosacral vaginal vault suspension, abdominal sacral colpopexy, colpocleisis, and sacrospinous ligament fixation. Patients will be asked to complete the Urinary Distress Inventory (UDI-6), American Urological Association Symptom Score (AUASS) at the time of consent. After informed consent is obtained for participation in our study, the patient will be randomized to the FAST or traditional retrograde fill voiding trial as delineated below. After their surgery, the morning of postoperative day 1, one of these methods to assess voiding dysfunction/urinary retention will be performed.

Retrograde fill voiding trial:

- Bladder drained using indwelling foley catheter placed in OR at completion of surgery
- Using the foley tubing the bladder is actively filled with 300cc normal saline or water
- The catheter tubing is removed
- The patient is instructed to void within 20 minutes
- The patient will subjectively quantify their FOS via VAS scale. However this information will not be used clinically
- If the patient has voided  $\geq 2/3$  ( $\geq 200\text{cc}$ ), she will be discharged without a foley
- If the patient voids  $< 2/3$  ( $< 200\text{cc}$ ) the amount instilled, she will be discharged home with a catheter, receive appropriate teaching for at-home maintenance of catheter and instructed to return to the office in 2-7 days in our office for a repeat retrograde voiding trial
- If the patient is unable to void at all, an indwelling foley catheter will be placed and she will follow up in 2-7 days in our office for a repeat retrograde voiding trial

For the FAST voiding trial the method will be:

- Bladder drained with indwelling foley catheter that was placed in OR at time of surgery
- Catheter bag removed and bladder then retrograde filled with 300cc normal saline or water
- The catheter is deflated and removed
- Patient is instructed to void within 20 minutes from time of completion of retrograde fill to void. 20 minutes is standard of care for the time allotted for a patient to void. Independent of bladder capacity, the average person will feel the urge to void at 150-200cc and will feel fullness and the urge to void at 300cc. If a patient does not feel the urge to void after 20 minutes, she will be discharged home with a catheter secondary to voiding dysfunction. She will receive appropriate teaching for at-home maintenance of catheter and instructed to return to the office in 2-7 days in our office for a repeat retrograde voiding trial
- The patient will subjectively quantify their FOS via VAS scale. If VAS scale  $\geq 50$  (equalling  $\geq 50\%$ ) then the catheter will remain out and no PVR will be measured
- If the VAS scale is from 0-49 (equalling 0-49%)
  - a PVR will be checked via bladder scan (bladder ultrasound)
  - PVR is  $< 500$  the patient will be discharged WITHOUT a catheter
  - PVR is  $\geq 500$  the patient will be discharged WITH a catheter
- If the patient is discharge with an indwelling foley catheter, she will follow up in 2-7 days in our office for a repeat test with a retrograde voiding trial, which is routine practice in our office

*Prior to retrograde fill, the bladder is drained by adjusting the foley catheter in situ. It is important to note that complete drainage of the bladder is not always possible as the catheter may become kinked during emptying or blocked from collapsed bladder tissue. After*



*adequate drainage, 300 cc saline or water is instilled into the bladder during retrograde fill.*

*In addition, intraoperatively, patients receive >1000cc fluid as well as 125 cc/hr of maintenance fluid. On average patients will make 50-100cc of urine an hour. Taking these clinical scenarios under consideration is important to understand how the PVR can be higher than the 300cc instilled in the bladder during the FAST method.*

Under anesthesia the bladder has a capacity ranging from 700-1000cc. Awake the bladder capacity is less, secondary to patient's urge to urinate secondary to bladder fullness which on average occurs at 300cc. The FAST voiding trial method showed that 500cc is an acceptable and safe amount in the bladder after midurethral sling placement if the patient states her FOS is >50% preoperatively<sup>9</sup>.

All patients discharged with a Foley catheter will be provided with the hospital's standard teaching for home care of Foley catheter. All patients will be instructed to notify their physician if they had any postoperative problems, specifically difficult voiding, or signs or symptoms of infection. All patients will be scheduled for a follow-up visit with the surgeon at 2 weeks and at 6 weeks postoperatively. This is standard in our practice regardless of participation in the research study. At these visits, patients will have another PVR obtained by bladder scan. The UDI-6 and AUASS will be re-administered at those visits as well.

We will collect information from their outpatient electronic medical records. Information collected will include age, race, body mass index, parity, severity of prolapse preoperatively, preoperative Urodynamics (UDS) including: cough stress test, leak point pressures, Urethral pressure profiles, presence of detrusor instability, use of antiincontinence medications, surgical history, urinalysis and PVR.

## 12. STATISTICAL ANALYSIS

- *Describe how your data will be used to test the hypotheses.*
- *State clearly what variables will be tested and what statistical tests will be used.*
- *Include sample size calculations.*
- *If this is a pilot study, state which variables will be examined for hypothesis generation in later studies.*

This is a randomized controlled trial in women to compare two methods of voiding after undergoing surgical repair for pelvic organ prolapse [POP]. The two methods are: the traditional retrograde bladder filling method and the force of stream trial (FAST). The study is designed as a non-inferiority trial to demonstrate that among patients who are discharged without a urinary catheter (because they passed the post-op voiding trial), the rate of catheterization within the six-week post-operative period in subjects undergoing the FAST voiding trial is not worse than in subjects undergoing the traditional retrograde voiding trial.

### **Specific Aims:**

1. The primary objective of the study is to compare Traditional voiding trial to FAST voiding trial with respect to the rate of catheterization within the six-week post-operative period in patients undergoing surgical repair of POP, among those discharged without a urinary catheter.
2. Secondary objectives include:
  - a. To compare the two voiding methods with respect to the proportion of patients discharged with a catheter (these are the subjects who fail the voiding trial)

- b. To compare the two voiding methods with respect to the incidence of any UTI within the six-week post-operative period
- c. To compare the two voiding methods with respect to the rate of emergency room visits or unexpected visits to the clinic within the six-week post-operative period for voiding dysfunction or suspected infection (this includes patients who were discharged with or without a urinary catheter)
- d. To compare the two voiding methods with respect to the time-to-catheterization post-discharge.
- e. To compare the two voiding methods with respect to patient satisfaction with post-operative bladder function using the American Urological Association Symptom Score and the Urinary Distress Inventory.

**Primary Outcome:**

The primary outcome variable of interest is the rate of catheterization within the six-week post-operative period following surgical repair of POP, among those discharged without a urinary catheter. (The primary outcome will be the overall rate (regardless of stratification) but catheterization rates by surgery type will also be examined.)

**Secondary Outcomes**

1. Proportion of patients discharged with a catheter (this is essentially the proportion of patients who failed the voiding trial)
2. Proportion of patients who reported *any* UTI within the six-week post-operative period. The number of UTIs reported by each patient during that period will also be recorded.
3. Proportion of patients with emergency room visits or unexpected visits to the Urogynecology clinic for voiding dysfunction or suspected infection, within the six-week post-operative period. The number of ER visits or unexpected clinic visits will also be recorded.
4. Time-to-catheterization post-discharge: This is the number of days from discharge to catheterization (within the 6-week period post-surgery). Subjects who are not catheterized by the end of the follow-up period will be considered 'censored'.
5. Patient satisfaction with postoperative bladder function (measured at baseline, 2-weeks post-op and 6 weeks post-op) using:
  - c. American Urological Association Symptom Score (AUASS)
  - d. Urinary Distress Inventory (UDI-6)

**Randomization:**

Subjects will be randomized in a 1-1 ratio to either the Traditional voiding trial or the FAST voiding trial. Randomization will be stratified by site (North Shore or Long Island Jewish), and within each site, by surgical type (apical prolapse surgery without sling or apical prolapse surgery with sling).

The Biostatistics Unit at the Feinstein Institute for Medical Research [BU-FIMR] will develop a randomization plan using the Biostatistics Randomization Management System [BRMS]. BRMS is a secure, HIPAA-compliant, web-based application that allows investigators to randomize subjects into randomized clinical trials (RCTs) using a personal computer with internet access. Randomization notifications are automatically sent to the PI and other authorized personnel. BRMS maintains compliance in RCTs. Details of the randomization procedure will be further developed upon approval of the protocol.

**Data Management**

REDCap (Research Electronic Data Capture), a secure, web-based application, will be used to store data from the trial.

**Intention-to-Treat (ITT)**

All subjects will be analyzed according to the intention-to-treat [ITT] principle. A patient will be considered evaluable and will be included in the intention-to-treat analysis if the patient was randomized to either voiding trial group and able to undergo the voiding trial after surgery. Analyses that take into account the actual voiding trial received will be carried out as a secondary analysis (per protocol [PP] analysis).

### **Interim Analysis and Early Stopping**

No interim analysis is planned for this study.

### **Statistical Methods:**

1. For the primary objective:

The test for non-inferiority will be carried out using a two-tailed 95% confidence interval for the difference in the rate of catheterization between the two voiding methods, within the six-week post-operative period,  $\delta$  ( $\delta$ =rate of catheterization in the FAST voiding trial – rate of catheterization in the Traditional voiding trial). This difference,  $\delta$ , is the margin of non-inferiority and will be set at 10%. If the upper confidence limit for the difference is  $<\delta$  ( $\geq\delta$ ) then we will conclude that the FAST voiding trial is non-inferior (inferior) to the Traditional voiding trial.

The test for non-inferiority will be performed only for the primary outcome variable of interest, i.e., catheterization within the six-week post-operative period among subjects who were discharged without needing a urinary catheter.

The test for non-inferiority will also be performed according to surgery type (the stratification variable).

2. For the secondary objectives:

- a. The chi-square test or Fisher's exact test, as appropriate, will be used to compare the two voiding methods with respect to the proportion of subjects who are sent home with a catheter due to failure of their voiding trial, post-surgery.
- b. The chi-square test or Fisher's exact test, as appropriate, will be used to compare the two voiding methods with respect to the proportion of subjects who present with *any* UTI within the six-week post-operative period. If feasible, the incidence of UTIs will be compared between the two voiding methods using the Incidence Density Ratio Method, or if feasible, Poisson regression methods.
- c. The chi-square test or Fisher's exact test, as appropriate, will be used to compare the two voiding methods with respect to the proportion of subjects who present to the emergency room or the urogynecology clinic (unexpectedly) due to voiding dysfunction or suspected infection, within the six-week post-operative period. If feasible, the incidence of ER visits or unexpected clinic visits will be compared between the two voiding methods using the Incidence Density Ratio Method, or if feasible, Poisson regression methods.
- d. The Kaplan-Meier product limit method will be used to estimate time-to-catheterization post-discharge and the two groups (Traditional Retrograde vs. FAST) will be compared using the log-rank test. Median time-to-catheterization will be estimated along with their corresponding 95% confidence intervals. The feasibility of this analysis will depend on the observed catheterization rates.
- e. A mixed models approach to repeated measures analysis of variance (MM-RMANOVA) will be carried out, separately, for each of the two measures of patient satisfaction with post-operative bladder function (AUASS and UDI-6). Each model will examine if the patterns of change in satisfaction scores across

time (baseline, 2 weeks post-op and 6 weeks post-op) differ between the two voiding methods. The models will include voiding group (Traditional/FAST), time (baseline, 2 weeks post-op and 6 weeks post-op) and a group-by-time interaction term. Data transformations may be employed if standard model assumptions are not met. If no suitable transformations are found, then appropriate non-parametric methods may be used instead.

A secondary analysis using logistic regression, will be carried out for each of the aims 2a, 2b and 2c, including explanatory variables such as age, site, and surgery type (sling vs. no sling).

**Sample Size Considerations:**

The proposed sample size for this one year study is a total of 154 *evaluable* subjects (n=77 randomized to each voiding group). A subject will be “evaluable” if she gets randomized and is able to undergo the voiding trial. A subject who is not able to undergo the voiding trial is considered “not evaluable” and would not be included in the analysis.

The study will be designed as a non-inferiority trial, where the FAST voiding trial will be considered non-inferior to the Traditional voiding trial if the difference in the rate of catheterization between the two groups within the six-week post-operative period among patients discharged without a catheter is less than  $\delta=10\%$  (i.e.  $\delta=10\%$ , the margin of non-inferiority). More formally, if the rates of catheterization during the six-week post-operative period are  $p_F$  and  $p_T$ , respectively for the FAST and Traditional voiding methods, then the null ( $H_0$ ) and alternative hypotheses ( $H_A$ ) are:

$$H_0: d = p_F - p_T \geq \delta \text{ vs.}$$

$$H_A: d = p_F - p_T < \delta$$

Based on the investigators’ clinical experience, it can be reasonably assumed that among those who pass the Traditional retrograde fill voiding trial, the rate of catheterization during the six-week post-operative period is about 5%. Further assuming that the rate of catheterization among those who pass the FAST voiding trial is the same as in the traditional voiding test (i.e. 5% as well), and using a non-inferiority margin,  $\delta$ , of 10%, then a sample size of 59 per group (n=118 total) will yield 80% power to determine that the FAST voiding trial is not inferior to the Traditional voiding trial ( $\alpha=0.05$ ).

Based on published manuscripts, about 30% of evaluable patients will fail either voiding trial, that is, approximately 30% in the traditional retrograde fill voiding trial arm will fail the test and similarly, approximately 30% in the FAST voiding trial arm will fail the test. Therefore, in order to obtain 118 subjects who pass the voiding test (59 per group), we would need to have a total of 154 subjects ( $118 \times 1.3=154$ ).

Randomized subjects will fall into three groups:

1. Subjects with a complication at surgery that would require prolonged catheterization immediately postoperative.
2. Subjects who fail either voiding test and are discharged home with a catheter (expected to be 25-26% based on published manuscripts)
3. Subjects passing either trial of void and discharged home without a catheter. This is the main population of interest that we want to examine to identify what proportion of subjects would end up needing a catheter ultimately in the 6-week postoperative period.

Below is a tabulation of sample size requirements for 80% power, using various assumptions for the rates of catheterization during the six-week post-operative period in each of the two

voiding methods, using a 2-sided alpha level of 0.05, and a non-inferiority margin,  $\delta$ , of 10%:

Traditional Voiding Method	FAST Voiding Method	Sample Size Per Method (N)
0.05	0.07	109
0.05	0.06	80
0.05	0.05	59
0.05	0.04	44
0.05	0.03	33

### 13. SPECIMEN BANKING

- *If specimens will be banked for future research, describe where the specimens will be stored, how long they will be stored, how they will be accessed and who will have access to the specimens*
- *List the information that will be stored with each specimen, including how specimens are labeled/coded*
- *Describe the procedures to release the specimens, including: the process to request release, approvals required for release, who can obtain the specimens, and the information to be provided with the specimens.*

Not applicable

### 14. DATA MANAGEMENT AND CONFIDENTIALITY

- *Describe the data and specimens to be sent out or received. As applicable, describe:*
  - *What information will be included in that data or associated with the specimens?*
  - *Where and how data and specimens will be stored?*
  - *How long the data will be stored?*
  - *Who will have access to the data?*
  - *Who is responsible for receipt or transmission of data and specimens?*
- *Describe the steps that will be taken to secure the data during storage, use and transmission.*

#### **Data Management**

REDCap (Research Electronic Data Capture), a secure, web-based application, will be used to store data from the trial.

#### **Confidentiality**

Confidentiality will be maintained by using patient identification numbers instead of names.

#### Storing Documents in Hard Copy

Original documents including consent forms that contain subjects' PHI, as well as questionnaires, will be stored in a locked cabinet within the office of Urogynecology, 865 Northern Blvd., Suite 202, Great Neck, NY 11021. These documents will be kept separately from any de-identified research data that will be stored electronically as mentioned below. IRB approved investigators will be the only individuals with access to research data that contains PHI.

#### Storing Documents Electronically

Any documents that contain subjects' PHI will be accessible on the Northwell Health network server through a password protected computer document/database. These documents are separated from any de-identified research data files. IRB approved investigators will be the only individuals with access to research data that contains PHI. De-identified data research files will be stored on the network server.

#### Storing Documents on Portable Electronic Devices

No PHI or research data will be stored on any Portable Electronic Devices (e.g., laptops, tablets, flash drives, etc.)

#### Emailing Data

Any research data that will be emailed will be de-identified and encrypted. PHI will not be emailed to any commercial email addresses (e.g., gmail, yahoo, hotmail, etc.)

**Data Disclosure/Publication**

Any data used in publications and presentations will be presented in an aggregate or de-identified format. Protected health information (PHI) will not be shared with entities outside of Northwell Health System for purposes of the research.

## 15. DATA AND SAFETY MONITORING PLAN

*A specific data and safety monitoring plan is only required for greater than minimal risk research. For guidance on creating this plan, please see the [Guidance Document](#) on the HRPP website.*

*Part I – this part should be completed for all studies that require a DSMP.*

*Part II – This part should be completed when your study needs a Data and Safety Monitoring Board or Committee (DSMB/C) as part of your Data and Safety Monitoring Plan.*

### Part I: Elements of the Data and Safety Monitoring Plan

- Indicate who will perform the data and safety monitoring for this study.*
- Justify your choice of monitor, in terms of assessed risk to the research subject's health and well being. In studies where the monitor is independent of the study staff, indicate the individual's credentials, relationship to the PI, and rationale for selection*
- List the specific items that will be monitored for safety (e.g. adverse events, protocol compliance, etc)*
- Indicate the frequency at which accumulated safety and data information (items listed in # above) will be reviewed by the monitor (s) or the DSMB/C.*
- Where applicable, describe rules which will guide interruption or alteration of the study design.*
- Where applicable, indicate dose selection procedures that will be used to minimize toxicity.*
- Should a temporary or permanent suspension of your study occur, in addition to the IRB, indicate to whom will you report the occurrence.*

The PI will monitor data, with emphasis on data integrity and patient welfare concerns including: recommendations concerning continuation or conclusion of the study, protection of the confidentiality of the trial data and the results of monitoring, review of data and study quality. Monitoring will occur on a monthly basis. We will have monthly meetings amongst the PI and co-investigators reviewing enrollment and any adverse events. In addition, we have bi-monthly morbidity and mortality rounds that allow us to examine closely any unexpected or adverse outcomes. Any adverse events, unanticipated problems, and protocol deviations will be reported to the IRB as per Northwell policy.

### Part II: Data and Safety Monitoring Board or Committee

- *When appropriate, attach a description of the DSMB.*
- *Provide the number of members and area of professional expertise.*
- *Provide confirmation that the members of the board are all independent of the study.*

*Not applicable*

## 16. WITHDRAWAL OF SUBJECTS

- *Describe anticipated circumstances under which subjects will be withdrawn from the research without their consent*
- *Describe procedures for orderly termination*
- *Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection.*

Candidates will be excluded from the study if ANY of the following apply:

1. Patients who underwent a surgery that requires long term catheterization (i.e fistula repair or urethral diverticulum)
2. Patients who sustained a cystotomy during surgery as our divisional protocol is to send these patients home with a Foley catheter for 5-14 days without a voiding trial
3. Patients with baseline urinary retention and the inability to urinate without catheterization

Listed in the informed consent given to the subject at the time of enrollment are instructions explaining how the subject may withdraw. In addition, at the time of enrollment, during the informed consent, this is described and reviewed with the subject. Subjects will be instructed to mail a letter to the PI stating their desire to withdraw from the study.

## 17. RISKS TO SUBJECTS

- *Describe any potential risks and discomforts to the subject (physical, psychological, social, legal, or other) and assess their likelihood and seriousness and whether side effects are reversible. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.*
- *Include risks to others , like sexual partners (if appropriate)*
- *Discuss why the risks to subjects are reasonable in relation to the anticipated benefits and in relation to the importance of the knowledge that may reasonably be expected to result.*
- *Describe the procedures for protecting against or minimizing any potential risks, including risks to confidentiality, and assess their likely effectiveness.*

Regardless of participation in this study, prior to discharge from the hospital, all participants will have a voiding trial performed to assess her bladder function. Urinary retention is a risk for any patient after prolapse or sling surgery.

Both methods we are investigating in this study have been shown to effectively assess postoperative bladder function. Based on the prior study by Tunistky-Bittin et al<sup>10</sup>, we do not expect any additional risk to the subject depending on what method is used to assess her ability to urinate.



There is a chance that the subject could be discharged without a catheter when she needs one. However, if she passes her voiding trial and is discharged without a catheter, she will be counseled on the signs and symptoms of urinary retention prior to discharge from the hospital. She will be given our office number and if after hours, a 24 hour emergency line to speak with the physician who will direct her to seek care at a local emergency room for catheter placement. This is routine practice and standard of care in our office, even if she was not participating in this study.

The risk of infection secondary to temporary placement of a catheter is 6% to 20% in patients undergoing prolapse and anti-incontinence surgeries<sup>10,13-17</sup>. Patients will be treated accordingly if infection is suspected after placement of catheter or found on routine urinalysis, as standard of care would dictate.

As in previous studies, patients who had the FAST voiding trial method did not have emergent or unexpected visits to the emergency room<sup>9,10</sup>. Outside of the risk of urinary retention and/or UTI, no additional risks are expected.

#### Other Risks

Some of the questions in the questionnaires may seem personal to the participants. They could feel embarrassed or stressed. They may ask to see the questions before deciding whether or not to take part in this study.

As in any research study, there is a risk of breach of confidentiality. However, we have a plan in place to minimize this risk, as detailed in the confidentiality section.

## 18. RESEARCH RELATED HARM/INJURY

- *Describe the availability of medical or psychological resources that subjects might need as a result of anticipated problems that may be known to be associated with the research.*
- *If the research is greater than minimal risk, explain any medical treatments that are available if research-related injury occurs, who will provide it, what will be provided, and who will pay for it.*

There is a chance that the subject could be discharged without a catheter when she needs one. However, if she passes her voiding trial and is discharged without a catheter, she will be counseled on the signs and symptoms of urinary retention prior to discharge from the hospital. She will be given our office number and if after hours, a 24 hour emergency line to speak with the physician who will direct her to seek care at a local emergency room for catheter placement. This is routine practice and standard of care in our office, even if she was not participating in this study.

All tests and procedures are standard of care and would be required, therefore included in their medical costs regardless of patients choice to participate

Subjects diagnosed with a urinary tract infection will be given prescriptions for the appropriate antibiotics.

## 19. POTENTIAL BENEFIT TO SUBJECTS

- *Explain what benefits might be derived from participation in the study, noting in particular the benefit over standard treatment (e.g. a once-a-day administration instead of four times a day, an oral formulation over an IV administration).*
- *Also state if there are no known benefits to subjects, but detail the value of knowledge to be gained*

This research may not benefit study participants directly. However, knowledge gained from this study may help physicians and patients in the future with regard to the best voiding trial for postoperative patients after vaginal apex prolapse surgery. We hope that our study results will encourage practitioners to evaluate their voiding protocols to decrease the catheterization rate and the time spent under observation after vaginal apex prolapse surgery.

## 20. PROVISIONS TO PROTECT PRIVACY INTERESTS OF SUBJECTS

- *Describe the methods used to identify potential research subjects, obtain consent and gather information about subjects to ensure that their privacy is not invaded.*
- *In addition consider privacy protections that may be needed due to communications with subjects (such as phone messages or mail).*

During the preoperative counseling visit at the urogynecology offices with either the PI or the co-investigators, patients will be identified for enrollment after inclusion and exclusion criteria are reviewed. Informed consent may be obtained at that time or in the preoperative holding

area in North Shore or Long Island Jewish Hospitals. Should a phone call be necessary to follow up on a missed appointment, HIPAA rules and regulations will be followed. No emails will be exchanged with subjects regarding the study.

## 21. COSTS TO SUBJECTS

- *Describe any foreseeable costs that subjects may incur through participation in the research*
- *Indicate whether research procedures will be billed to insurance or paid for by the research study.*

There are no direct costs to patients. Study related procedures included the trial of void, foley catheter, and bladder scan PVR are standard of care in our practice, regardless of participation in the research study.

## 22. PAYMENT TO SUBJECTS

- *Describe the amount of payment to subjects, in what form payment will be received and the timing of the payments.*

No payments will be made to subjects.

## 23. CONSENT PROCESS

*If obtaining consent for this study, describe:*

- *Who will be obtaining consent*
- *Where consent will be obtained*
- *Any waiting period available between informing the prospective participant and obtaining consent*
- *Steps that will be taken to assure the participants' understanding*
- *Any tools that will be utilized during the consent process*
- *Information about how the consent will be documented in writing. If using a standard consent form, indicate such.*
- *Procedures for maintaining informed consent.*

After determination of eligibility based on inclusion/exclusion criteria the patient will be consented for the study related procedures. The subject must provide written informed consent to participate prior to the conduct of the study specific procedure. Only IRB approved personnel will obtain informed consent from participants. The participant may be consented in the clinic for the department of urogynecology or in the preoperative holding unit prior to her surgery. If a patient is eligible to enroll in the study, the nature and purpose of the study will be explained to the subject with a witness present. The participant will also be informed about the procedures, risks, and voluntary nature of the study during the consent discussion. The subject will be allowed to ask questions throughout the counseling process. The subject will review and sign the written Informed Consent Form indicating informed. The participant will be given a copy of the consent form.

*In the state of NY, any participants under the age of 18 are considered children. If your study involves children, additional information should be provided to describe:*

- *How parental permission will be obtained*
- *From how many parents will parental permission be obtained*
- *Whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. The process used to determine these individual's authority to consent for the child should be provided*
- *Whether or not assent will be obtained from the child*
- *How will assent be documented*
- *Whether child subjects may be expected to attain legal age to consent to the procedures for research prior to the completion of their participation in the research. If so, describe the process that will be used to obtain their legal*

*consent to continue participation in the study. Indicate what will occur if consent is not obtained from the now-adult subjects.*

*Not applicable*

*If the study involves cognitively impaired adults, additional information should be provided to describe:*

- *The process to determine whether an individual is capable of consent*
- *Indicate who will make this assessment*
- *The plan should indicate that documentation of the determination and assessment will be placed in the medical record, when applicable, in addition to the research record.*
- *If permission of a legally authorized representative will be obtained,*
  - *list the individuals from who permission will be obtained in order of priority*
  - *Describe the process for assent of subjects; indicate whether assent will be required of all, some or none of the subjects. If some, which subjects will be required to assent and which will not.*
  - *If assent will not be obtained from some or all subjects, provide an explanation as to why not*
  - *Describe whether assent will be documented and the process to document assent*
  - *Indicate if the subject could regain capacity and at what point you would obtain their consent for continued participation in the study*

*Not applicable*

*If the study will enroll non-English speaking subjects:*

- *Indicate what language(s) other than English are understood by prospective subjects or representatives*
- *Indicate whether or not consent forms will be translated into a language other than English*
- *Describe the process to ensure that the oral and written information provided to those subjects will be in that language*
- *If non-English speaking subjects will be excluded, provide a justification for doing so*

Our patient population includes English, Spanish, Arabic, Chinese/Mandarin languages. Using the available short, generic foreign language consent forms available on the IRB website and the translator phone service readily available to all investigators, non-English speaking subjects can be approached for enrollment. The potential subject will be offered access to free interpretation services through telephone or on-site certified translators. The subject will have the right to waive the interpretation services. Documentation of the name of the interpreter and the interpreter telephone ID number will be written in the medical record and on the informed consent form and short form.

**24. WAIVER OR ALTERATION OF THE CONSENT PROCESS**  N/A

*Complete this section if you are seeking an alteration or complete waiver of the consent process.*

- *Describe the possible risks of harm to the subjects involved in this study and explain why the study involves no more than minimal risk to the subject:*
- *Explain why the waiver/ alteration will not adversely affect the rights and welfare of subjects*
- *Explain why it is impracticable to conduct this research if informed consent is required*
- *If appropriate, explain how the subjects will be provided with additional pertinent information after participation. If not appropriate to do so, explain why.*

*Complete this section if you are obtaining informed consent but you are requesting a waiver of the documentation of consent (i.e., verbal consent will be obtained). To proceed with a waiver based on these criteria, each subject must be asked whether they wish to have documentation linking them to this study. **Only complete subsection 1 OR subsection 2.***

**SUBSECTION 1**

- *Explain how the only record linking the subject to the research would be the consent document.*
- *Explain how the principal risk of this study would be the potential harm resulting from a breach in the confidentiality*
- *Indicate whether or not subjects will be provided with a written statement regarding the research.*

**SUBSECTION 2**

- *Describe the possible risks of harm to the subjects involved in this study and explain why the study involves no more than minimal risk.*
- *Confirm that the research only involves procedure for which consent is not normally required outside the research context.*
- *Indicate whether or not subjects will be provided with a written statement regarding the research.*

**25. WAIVER OF HIPAA AUTHORIZATION**  N/A

**Complete this section if you seek to obtain a full waiver of HIPAA authorization to use and/or disclose protected health information.**

- Describe the risks to privacy involved in this study and explain why the study involves no more than minimal risk to privacy:
- Describe your plan to protect identifiers from improper use or disclosure and to destroy them at the earliest time.
- Indicate why it is not possible to seek subjects' authorization for use or disclosure of PHI.
- Indicate why it is not possible to conduct this research without use or disclosure of the PHI.
- Indicate if PHI will be disclosed outside NSLIJ Health System, and if so, to whom. Note: PHI disclosed outside NSLIJ Health System, without HIPAA authorization needs to be tracked. Please see guidance at [www.nslj.com/irb](http://www.nslj.com/irb) for information about tracking disclosures.

**Complete this section if you seek to obtain a partial waiver of the patient's authorization for screening/recruitment purposes (i.e., the researcher does not have access to patient records as s/he is not part of the covered entity)**

Note: Information collected through a partial waiver for recruitment cannot be shared or disclosed to any other person or entity.

- Describe how data will be collected and used:
- Indicate why you need the PHI (e.g. PHI is required to determine eligibility, identifiers are necessary to contact the individual to discuss participation, other)
- Indicate why the research cannot practicably be conducted without the partial waiver (e.g. no access to medical records or contact information of the targeted population, no treating clinician to assist in recruitment of the study population, other)

*Not applicable*

## 26. VULNERABLE POPULATIONS:

Indicate whether you will include any of these vulnerable populations. If indicated, submit the appropriate appendix to the IRB for review:

- Children or viable neonate
- Cognitively impaired
- Pregnant Women, Fetuses or neonates of uncertain viability or nonviable
- Prisoners
- NSLIJ Employees, residents, fellows, etc
- poor/uninsured
- Students
- Minorities

- Elderly*  
 *Healthy Controls*

*If any of these populations are included in the study, describe additional safeguards that will be used to protect their rights and welfare.*

Elderly subjects' ability to consent will be screened for by the PI or co-investigators. PI and co-investigators have numerous conversations with the potential subjects prior to surgical planning, preoperative consent, and possibly consent for research participation. The investigators' interactions with the potential subject will allow assessments to be made whether the subject can sign informed consent for their surgery. Should the investigator determine the subject cannot sign the informed consent for their surgical procedure due to impaired decision-making ability, the subject is not eligible for enrollment due to this impairment as well.

## 27. MULTI-SITE HUMAN RESEARCH (COORDINATING CENTER)

*If this is a multi-site study where you are the lead investigator, describe the management of information (e.g. results, new information, unanticipated problems involving risks to subjects or others, or protocol modifications) among sites to protect subjects.*

*Not applicable*

## 28. REFERENCES/BIBIOGRAPHY

*Provide a reasonable list of references directly related to the study. Any diagrams for new medical devices or brief reprints from journals might also prove useful.*

### Reference:

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4. Stav K, Dwyer PL, Rosamilia A, et al. Repeat synthetic mid urethral sling procedure for women with recurrent stress urinary incontinence. *J Urol* 2010;183:241-6.
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7. Kleeman S, Goldwasser S, Vassallo B, Karram M. Predicting postoperative voiding efficiency after operation for incontinence and prolapse. *Am J Obstet Gynecol* 2002;187:49-52.
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13. Sutkin G, Lowder JL, Smith KJ. Prophylactic antibiotics to prevent urinary tract infection during clean intermittent self-catheterization (CISC) for management of voiding dysfunction after prolapse and incontinence surgery: a decision analysis. *Int Urogynecol J Pelvic Floor Dysfunct* 2009;20:933-8.
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16. Ward KL, Hilton P, Uk, Ireland TVTTG. Tension-free vaginal tape versus colposuspension for primary urodynamic stress incontinence: 5-year follow up. *BJOG* 2008;115:226-33.
17. Liapis A, Bakas P, Creatsas G. Long-term efficacy of tension-free vaginal tape in the management of stress urinary incontinence in women: efficacy at 5- and 7-year follow-up. *Int Urogynecol J Pelvic Floor Dysfunct* 2008;19:1509-12.