Study Title:

Are **Vi**rtual Visits for **D**elivery of Postoperative Care Following Urogynecologic Surgery **E**qual to **O**ffice Visits? The VIDEO Randomized Trial

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A. **BACKGROUND AND SIGNIFICANCE**

Telehealth refers to the dissemination of health-related information, delivering services such as remove patient monitoring, and the provision of clinical care to patients via telecommunications technology such as telephone, video conferencing, text messaging, and email.[1] The pandemic has catalyzed rapid adoption of telehealth, with an increase in the proportion of telehealth visits in some healthcare systems from less than 100 too greater than 600 video visits per day.[2] Telehealth increases efficiency and access to health services. Although face-to-face interactions may be preferred in some circumstances, telehealth visits can improve access to healthcare for patients with transportation challenges, work schedule limitations, or physical disability and may be considered as an alternative to office visits.[2-3]

Delivery of postoperative care via telehealth platforms has been successfully incorporated into other fields such as urology, pediatric surgery, and general surgery.[4-5] Interactive, face-to-face contact between patient and provider in real-time through videoconferencing allows for examination of surgical sites, catheters and other drains, in addition to discussion of surgical recovery. Prior studies suggest that telehealth enhances patient satisfaction and improves patient engagement and adherence with care.[1,6-7] When compared with traditional methods of healthcare delivery, telehealth provides comparable health outcomes without compromising the patient-physician relationship.[1]

Telehealth has immense potential to improve healthcare quality by improving patient satisfaction and clinical outcomes while minimizing adverse events. Postoperative patient satisfaction is an indicator of overall surgical quality of care.[4,6] Studies focusing on patient-centered outcomes associated with videoconference technology for delivery of postoperative care following pelvic reconstructive surgery are limited. To date, only two randomized controlled trials have been published evaluating patient satisfaction with telehealth visits in the urogynecologic population.[4,6] The intervention evaluated by Thompson et al. was limited to telephone visits only for postoperative follow-up.[4] The study by Lee et al. included only patients undergoing pelvic organ prolapse surgery with a follow-up call placed 48 to 72 hours after discharge and both video and in-person groups returning to the office at 90 days after surgery; patient satisfaction was evaluated at the 30-day in-person versus virtual visit.[6] Both trials demonstrated that postoperative telehealth visits were non-inferior to traditional in-office visits based on patient satisfaction; with no difference in healthcare utilization, complication rates, or clinical outcomes based on validated questionnaires. Additionally, several studies have demonstrated a positive correlation between patient preparedness for pelvic organ prolapse and/or anti-incontinence surgery and postoperative satisfaction, perioperative outcomes, postoperative symptom and quality of life improvement, and perceived complications.[8-10]

The proposed VIDEO randomized trial will help inform clinical practice regarding the utility and perceived value of videoconferencing for postoperative care of urogynecologic patients by comparing patient satisfaction with virtual video visits and traditional in-office visits after pelvic organ prolapse and/or anti-incontinence surgery. The study will secondarily investigate other important components of healthcare quality, including safety and clinical outcomes, by comparing postoperative healthcare resource utilization and adverse events within 12 weeks after urogynecologic surgery.

B. **SPECIFIC AIMS**

Primary aim:

- To compare patient satisfaction with their postoperative visit between patients receiving in-office versus virtual-video postoperative visits at 6 weeks after surgery.
  We hypothesize that patient satisfaction with a virtual postoperative visit will be noninferior to patient satisfaction with an in-office postoperative visit

Secondary aims:

- To compare healthcare resource utilization after the postoperative visit up to 12 weeks following urogynecologic surgery between patients receiving in-office versus virtual-video postoperative visits.
  We hypothesize that the virtual group will be noninferior to the in-office group based on healthcare resource utilization after the postoperative visit up to 12 weeks following surgery.

- To compare adverse events after the postoperative visit up to 12 weeks following urogynecologic surgery between patients receiving in-office versus virtual-video six-week postoperative visits.
  We hypothesize that the virtual group will be noninferior to the in-office group based on adverse events after the postoperative visit up to 12 weeks following surgery.

- To evaluate patient and provider preferences/attitudes toward in-office versus virtual-video postoperative visits

C. **RESEARCH PLAN**

Overall Study Design

- The study is a randomized controlled noninferiority trial evaluating patient satisfaction with in-office versus virtual-video postoperative visits at six weeks following urogynecologic surgery. We aim to assess whether the intervention of virtual postoperative visit via videoconference technology is noninferior to the standard/traditional in-office postoperative visit for our primary outcome of patient satisfaction. The recruitment period will be 15 months (January 1, 2023 to March 31, 2024). The follow-up period for each participant will be 12 weeks after surgery.

Outcome Measures

- Primary Outcome:
  - Patient satisfaction as measured by the Patient Satisfaction Questionnaire-18 at the 6-week postoperative visit
- Secondary Outcomes:
  - Healthcare resource utilization as measured by patient-initiated phone calls, unscheduled in-person/virtual office visits, emergency room or urgent care visits, and inpatient readmissions after the scheduled postoperative visit up to 12 weeks following surgery
  - Adverse events after the scheduled postoperative visit up to 12 weeks following surgery
  - Patient and provider preferences/attitudes toward virtual or office visits

Eligibility Criteria

- All patients of the Center for Urogynecology and Pelvic Reconstructive Surgery in the Department of Obstetrics/Gynecology and Women's Health Institute at the Cleveland Clinic (Main Campus, Fairview Hospital, Hillcrest Hospital, Medina Hospital and Beachwood Ambulatory Surgery Center) scheduled to undergo major or minor surgery for pelvic organ prolapse and/or urinary incontinence
    - Major surgery[+]
        - Minimally invasive (laparoscopic or robotic) sacrocolpopexy
        - Vaginal colpopexy (intraperitoneal or extraperitoneal)
        - Vaginal or minimally invasive (laparoscopic or robotic) hysteropexy (uterine suspension)
        - Obliterative procedures (colpocleisis)

        [+] *Additional procedures accompanying the above major operations may include: hysterectomy (total or supracervical), trachelectomy, salpingectomy or salpingo-oophorectomy, anterior and/or posterior colporrhaphy with perineorrhaphy, enterocele repair, minimally invasive Burch colposuspension or paravaginal defect repair, vaginal mesh removal or revision, placement of vaginal graft, or placement of mid-urethral sling*
    - Minor surgery
        - Isolated colporrhaphy (anterior/posterior) and/or perineorrhaphy
        - Placement of mid-urethral sling
        - Vaginal mesh removal or revision
- Inclusion Criteria
    - Age greater than 18 years old
    - Has technological capability to participate in videoconferencing (high-speed internet access with desktop computer or mobile device)
    - Has decision-making capacity and able to provide informed consent for research participation
    - Able to speak and read English
- Exclusion Criteria
    - Patient requested to physically come in the office or have a virtual visit for her postoperative visit
    - Planned concomitant surgery with another surgical team
    - Office follow-up is deemed medically necessary by provider/surgeon

Study Procedures

- Screening and Recruitment
    - Participants will be prospectively identified by the primary surgeon during the patient's initial consultation when the decision is made to proceed with surgery for pelvic organ prolapse and/or urinary incontinence.
    - Compensation will be provided to trial participants with a total of $50 in the form of a check in the mail from Cleveland Clinic. The payment will be prorated according to the procedures completed. The participant will receive $10 after completion of the Patient Preparedness Questionnaire pre-operatively, $20 after completion of the Patient Satisfaction Questionnaire-18 postoperatively, and $20 after completion of the Patient Postoperative Visit Questionnaire postoperatively. Addresses for mailing of checks will be verified.
    - Reasons for declining participation in the study will be collected and recorded separately.

- Consent/Assent Process
    - Patients who agree to participate will sign a consent form. The consent interview will occur during the participant's preoperative visit at the Center for Urogynecology and Pelvic Reconstructive Surgery at Cleveland Clinic. Alternatively, the patient will be able to provide consent for research participation remotely via electronic signature using the DocuSign eConsent Platform.

- Randomization:
    - Trial participants will be randomized to one of two arms:
        - 1) **Office Visit** (*Control Arm*): Patients randomized to the control arm will be scheduled for and follow up with the surgeon or an advanced practice provider via an in-office visit at 6 weeks after the planned date of surgery. If the surgery were to be rescheduled to a future date, the postoperative visit will be moved accordingly to ensure follow-up occurs at the 6-week postoperative period.
        - 2) **Virtual Visit** (*Intervention Arm*): Patients randomized to the intervention arm will be scheduled for and follow up with the surgeon or an advanced practice provider via a virtual visit using videoconference technology at 6 weeks after the anticipated date of surgery. If the surgery were to be rescheduled to a future date, the postoperative visit will be moved accordingly to ensure follow-up occurs at the 6-week postoperative period.
    - Stratified block randomization will be used to ensure that the number of participants is equally distributed among the study groups and stratified by surgery level (major, minor). The allocation sequence will be generated with block size of 4 using computer software. Randomization will be implemented with the REDCap Randomization module. Randomization schedule can only be accessed by a research personnel not directly involved in patient care. The patient's 6-week postoperative visit will be scheduled according to her assigned group.

- Study instruments:
    - Study instruments will be administered at the preoperative visit and the 6-week postoperative visit. The questionnaires for this study include the Patient Preparedness Questionnaire (PPQ), the Patient Satisfaction Questionnaire-18 (PSQ-18), and modified patient and provider preference questionnaires entitled, Patient Postoperative Visit Questionnaire and Provider Postoperative Visit Preference Questionnaire.
    - The PPQ will be administered during the preoperative visit to assess patient knowledge and preparedness for surgery, which has been demonstrated in other studies to impact postoperative satisfaction, perceived complications, and drug utilization.[10-11] The PPQ is a 11-item questionnaire scored on a six-point Likert scale and has responses ranging from 1 (strongly agree) to 6 (strongly disagree).[9] The questionnaire for this study will utilize the same six-point scale with a reversed scoring system, ranging from 1 (strongly disagree) to 6 (strongly agree). Although there are currently no validated measures to assess surgical preparedness in urogynecology, the PPQ has been used in several studies assessing surgical preparedness in women undergoing pelvic organ prolapse and/or stress urinary incontinence.[8,12] These studies utilized the same cutoff score for question 11 (i.e., an answer of "strongly agree" to the question "overall, I feel prepared for my upcoming surgery") to define meeting criteria for preoperative preparedness.
    - The PSQ-18 will be administered after the 6-week postoperative virtual or in-office visit to assess patient satisfaction with their postoperative visit. The PSQ-18 is a

validated 18-item questionnaire developed to evaluate satisfaction with medical care in seven domains, namely general satisfaction, technical quality, interpersonal manner, communication, financial aspects, time spent with doctor, and accessibility and convenience. Responses are scored on a five-point Likert scale, ranging from 1 (strongly disagree) to 5 (strongly agree). The total score for the questionnaire ranges from 18 (dissatisfaction with medical care) to 90 (highest satisfaction with medical care). The questionnaire has been studied extensively and used as a valid and reliable measure of satisfaction in a variety of settings, including postoperative care after pelvic organ prolapse surgery and minimally invasive gynecologic surgery.[5-6]

- Currently, there are no validated tools to assess patient or provider attitudes towards telemedicine in urogynecology. A customized patient questionnaire "Patient Postoperative Visit Questionnaire" will be administered after the six-week postoperative visit to assess patient's preference/attitude towards virtual and office visits. The items in this questionnaire were adapted from a survey used in a cross-sectional study of patients and clinicians (psychiatry, neurology, cardiology, oncology, and primary care) participating in telehealth virtual video visits in an academic health system.[3] The questionnaire was originally developed by the MGH Center for TeleHealth leadership and Mongan Institute Health Policy Center research team and consists of 7 comparative questions about office visits and virtual video visits. The customized survey includes an open-ended question, allowing the patient to select their preference for in-person or virtual visits for future postoperative visits and to specify their reason/s.
- A provider preference questionnaire "Provider Postoperative Visit Preference Questionnaire" will be administered to the surgeon or advanced practice provider after completion of the six-week postoperative visit to assess provider preference/attitudes. The questionnaire was adapted from the provider survey utilized by Donelan et al. and consists of 10 comparative questions about office visits and virtual video visits.[3]
- All questionnaires can be completed either with paper forms or electronically through Research Electronic Data Capture (REDCap), depending on patient/provider preference. Study participants will be reminded within 48 to 72 hours after their visit regarding completion of their questionnaires by telephone call using a standardized phone script or by text or email message after their preoperative visit and their 6-week postoperative visit. Reminders for survey completion will be sent up to two times.

- Preoperative Visit
  - The preoperative visit will take place per our standard protocol, which includes a thorough discussion of the surgical purpose, alternatives, benefits, risks/complications, and postoperative expectations. Following informed consent, study-related procedures during the preoperative visit include study randomization, and scheduling of postoperative visits per study protocol. The PPQ will also be administered during this visit.

- Postoperative Visit (6 weeks)
  - Prior to the 6-week postoperative visit, a study investigator will initiate a reminder to the participant by phone, email or text to remind her of her upcoming appointment using a standard script. A checklist of discussion points will be used to standardize counseling and evaluation during the 6-week postoperative visit. Both office and virtual visits will be conducted in the same manner: The provider

will inquire about any concerns the patient has regarding recovery, followed by any unanticipated healthcare encounters at outside facilities. These outside healthcare encounters will be documented by the provider in their Epic note to facilitate data collection by the study investigators. The provider will review key aspects of postoperative care (bowel function, urinary function, presence of vaginal bleeding, dietary status, and ambulatory status), postoperative instructions and precautions, findings and procedures done during surgery, and pathology results (if applicable). The provider will then visually examine surgical sites and document their findings in their Epic note. The provider will inquire about any additional questions from the patient and perform additional evaluation/treatments per standard of care. The PSQ-18 and the Patient Postoperative Visit questionnaire will be administered after this visit. The patient may be contacted for up to two times by a study investigator via phone, text or email within 48 to 72 hours after the visit regarding completion of study questionnaires using a script.

- Provider Recruitment and Study Procedures
    - Surgeons and advanced practice providers will be educated about the study during the Urogynecology Section Research Meeting as part of the provider recruitment process.
    - After the six-week virtual or in-office visit, the provider will fill out the Provider Information Sheet and the Provider Postoperative Visit Preference Questionnaire. The provider will complete the questionnaire at the end of the visit. If this is not feasible, the provider will be sent a text reminder for up to two times to their Cleveland Clinic issued phone number within 48 to 72 hours after the visit.

	Preoperative Visit	Day of Surgery	Postoperative Visit (6 weeks)	End of study follow-up (12 weeks after surgery)
Questionnaire: PPQ	X			
Questionnaire: PSQ-18			X	
Questionnaire: Patient Postoperative Visit			X	
Questionnaire: Provider Postoperative Visit Preference			X	
Data collection: Demographic and baseline clinical characteristics	X			
Data collection: Perioperative characteristics		X		
Data collection: Postoperative healthcare resource utilization, adverse events			X	X

D. **DATA ANALYSIS PLAN**

- Data Collection

    - A) Demographic data will include the following:
        - Date of preoperative visit (MM/DD/YYYY)
        - Route of preoperative visit with surgeon (in-office/virtual)
        - MRN
        - Age (years)
        - Race
        - Ethnicity
        - Marital status
        - Distance from home to clinic (miles)
        - Vaginal parity
        - Menopausal state
        - Current tobacco use (Y/N)
        - BMI (kg/m^2)
        - Comorbid conditions (MI, CHF, peripheral vascular disease, cerebrovascular disease, dementia, chronic pulmonary disease, connective tissue disease, ulcer disease, mild liver disease, diabetes, diabetes with end organ damage, hemiplegia, moderate or severe renal disease, any tumor without metastasis, leukemia, lymphoma, moderate or severe liver disease, metastatic solid tumor, AIDS)
        - Charlson Comorbidity Index (CCI) score
            - *Calculation for CCI: diabetes with complications, hemiplegia/paraplegia, renal disease, and malignancies, age 60-69 are assigned a score of 2; age 70-79 moderate/severe liver disease is assigned a score of 3; metastatic solid tumour and AIDS/HIV are assigned a score of 6; the remaining comorbidities are assigned a score of 1*
        - Prior prolapse surgery (Y/N; if Y, specify)
        - Prior anti-incontinence surgery (Y/N; if Y, specify)
        - Preoperative prolapse overall stage based on POP-Q exam (0, I, II, III, IV)
        - Preoperative POP-Q points (Aa, Ba, C, GH, PB, TVL, Ap, Bp, D)
        - Preference for text or email reminder communication
        - Preferred mobile phone number or email address

    - B) Perioperative data will include the following:
        - Date of surgery (MM/DD/YYYY)
        - Location of OR facility
        - Surgery level (Minor, Major)
        - Surgery type
        - Concomitant procedures
        - Operative time (minutes)
        - Estimated blood loss (ml)
        - Intraoperative complications (bladder injury, ureteral kinking, bowel injury, vascular injury, EBL ≥300 ml, transfusion, conversion to open procedure, other-specify)
        - Hospital length of stay (no. of hours if <24 hours; no. of days if >24 hours)
        - If patient was admitted, was the admission planned (Y/N)

- If N, specify reason for postoperative admission
- Voiding trial results (Pass/Fail)
  - If Fail, select outcome: foley catheter reinserted, patient taught intermittent self-catheterization
- Postoperative prescriptions at discharge (name, dosing, quantity)

- C) Six-week postoperative data will include the following:
  - Date of postoperative visit (MM/DD/YYYY)
  - Number of days postop at 6-week visit
  - Route of postoperative visit (in-office, virtual)
    - If virtual, was an in-office visit recommended for further evaluation (Y/N); reason for office evaluation (specify)
    - If virtual, did the patient require assistance with using video conference technology prior to their scheduled appointment (Y/N)
    - If virtual, were there any technological difficulties during the visit (Y/N)
  - Did the patient cross-over to the other group at any point before the 6-week visit (Y/N)?
  - Provider conducting postoperative visit (APRN, MD, other-specify)
  - Abdominal exam performed (Y/N); if Y, list findings (normal, abnormal-specify)
  - Pelvic/vaginal exam performed (Y/N); if Y, list findings (normal, abnormal-specify)
  - Patient-initiated phone call to surgeon's office prior to 6-week postoperative visit (Y/N); if Y,
    - Total number of phone calls (No. of occurrences)
    - Date of phone call #1 (MM/DD/YYYY)
      - Reason/s for phone call #1
      - Outcome of phone call (counseling/reassurance, prescription sent, new order placed, new office/virtual appointment scheduled, advised to go to ED/urgent care, provider placed follow-up call to patient the next day, other-specify)
    - Date of phone call #2 (MM/DD/YYYY)
      - Reason/s for phone call #2
      - Outcome of phone call
    - Date of phone call #3 (MM/DD/YYYY)
      - Reason/s for phone call #3
      - Outcome of phone call
  - Unanticipated outpatient (office/virtual) visits to surgeon's office prior to 6-week postoperative visit (Y/N); if Y,
    - Total number of outpatient visits including office voiding trials (No. of occurrences)
    - Total number of voiding trial visits (No. of occurrences)
    - Date of outpatient visit #1 (MM/DD/YYYY)
      - Reason/s for outpatient visit
      - Outcome of outpatient visit (counseling/reassurance, prescription sent, new order placed, new office/virtual appointment scheduled, advised to go to ED/urgent care, hospital/direct admission, reoperation, provider/patient to place follow-up call, other-specify)

- Date of outpatient visit #2 (MM/DD/YYYY)
    - Reason/s for outpatient visit
    - Outcome of outpatient visit
- Date of outpatient visit #3 (MM/DD/YYYY)
    - Reason/s for outpatient visit
    - Outcome of outpatient visit

▪ Emergency department or urgent care visits prior to 6-week postoperative visit (Y/N); if Y,
- Total number of ED/urgent care visits (No. of occurrences)
- Date of ED visit #1 (MM/DD/YYYY)
    - Reason/s for ED visit
    - Outcome of ED visit (discharge, readmission, reoperation, other-specify)
- Date of ED visit #2 (MM/DD/YYYY)
    - Reason/s for ED visit
    - Outcome of ED visit (discharge, readmission, reoperation, other-specify)

▪ Hospital readmissions prior to 6-week postoperative visit (Y/N); if Y,
- Total number of hospital readmissions
- Date of readmission #1
    - Reason/s for readmission
    - Outcome of readmission (discharge, reoperation, other-specify)
    - Hospital length of stay (no. of days)

▪ Adverse events prior to postoperative visit (Y/N); if Y, specify (urinary tract infection, neurologic injury, hemorrhage/hematoma, blood transfusion, wound infection and cellulitis, seroma, abscess, pyelonephritis, sepsis, vaginal fistula, vaginal dehiscence, deep venous thrombosis, pneumonia, drainage of abscess, delayed gastrointestinal injury, delayed genitourinary injury, ileus, small bowel obstruction, pulmonary embolism, myocardial infarction, cerebrovascular accident and stroke, death, mesh complication, readmission, reoperation)

o D) <u>Twelve-week postoperative data</u> will include the following:

▪ End of follow-up (i.e., date marking 6 weeks after the patient's scheduled 6-week postoperative visit) (MM/DD/YYYY)
▪ Number of days postop at date above
▪ Patient-initiated phone call to surgeon's office during the next six weeks following the scheduled 6-week postoperative visit (Y/N); if Y,
- Total number of phone calls (No. of occurrences)
- Date of phone call #1 (MM/DD/YYYY)
    - Reason/s for phone call #1
    - Outcome of phone call (counseling/reassurance, prescription sent, new order placed, new office/virtual appointment scheduled, advised to go to ED/urgent care, provider placed follow-up call to patient the next day, other-specify)
- Date of phone call #2 (MM/DD/YYYY)
    - Reason/s for phone call #2
    - Outcome of phone call

- Unanticipated outpatient (office/virtual) visits to surgeon's office during the next six weeks following the scheduled 6-week postoperative visit (Y/N); if Y,
    - Total number of outpatient visits including office voiding trials (No. of occurrences)
    - Total number of voiding trial visits (No. of occurrences)
    - Date of outpatient visit #1 (MM/DD/YYYY)
        - Reason/s for outpatient visit
        - Outcome of outpatient visit (counseling/reassurance, prescription sent, new order placed, new office/virtual appointment scheduled, advised to go to ED/urgent care, hospital/direct admission, reoperation, provider/patient to place follow-up call, other-specify)
    - Date of outpatient visit #2 (MM/DD/YYYY)
        - Reason/s for outpatient visit
        - Outcome of outpatient visit
- Emergency department or urgent care visits during the next six weeks following the scheduled 6-week postoperative visit (Y/N); if Y,
    - Total number of ED/urgent care visits (No. of occurrences)
    - Date of ED visit #1 (MM/DD/YYYY)
        - Reason/s for ED visit
        - Outcome of ED visit (discharge, readmission, reoperation, other-specify)
    - Date of ED visit #2 (MM/DD/YYYY)
        - Reason/s for ED visit
        - Outcome of ED visit (discharge, readmission, reoperation, other-specify)
- Hospital readmissions during the next six weeks following the scheduled 6-week postoperative visit (Y/N); if Y,
    - Total number of hospital readmissions
    - Date of readmission #1
        - Reason/s for readmission
        - Outcome of readmission (discharge, reoperation, other-specify)
        - Hospital length of stay (no. of days)
- Adverse events during the next six weeks following the scheduled 6-week postoperative visit (Y/N); if Y, specify (urinary tract infection, neurologic injury, hemorrhage/hematoma, blood transfusion, wound infection and cellulitis, seroma, abscess, pyelonephritis, sepsis, vaginal fistula, vaginal dehiscence, deep venous thrombosis, pneumonia, drainage of abscess, delayed gastrointestinal injury, delayed genitourinary injury, ileus, small bowel obstruction, pulmonary embolism, myocardial infarction, cerebrovascular accident and stroke, death, mesh complication, readmission, reoperation)

- Power Analysis and Sample Size Calculation
    - The primary outcome of this study is to compare patient satisfaction between patients scheduled for office versus virtual six-week postoperative visits.
    - A priori sample size calculation determined that 100 participants (50 per group) would allow for 80% power to assess a noninferiority margin of 5 points on the

total PSQ-18, with a SD of 10 and significance level of 0.05. A minimum important difference has not been reported for the PSQ-18; however, previous studies using this tool demonstrated SD for total PSQ-18 score ranging between 2.6 and 11.8 and used a 5-point interval for the noninferiority margin.[6,13] To account for an anticipated attrition rate of approximately 5%, we aimed to enroll a total of 106 participants (53 per group).

- Statistical Analysis
    - Patient satisfaction (PSQ-18) total scores, as well scores in each of the 7 PSQ-18 domains, will be treated as continuous data and checked for normality. Healthcare utilization will be analyzed individually (number of phone calls, number of outpatient visits, number of emergency department or urgent care visits, number of hospital readmissions), as well as a composite of all encounter types. Adverse events will be analyzed independently but also as a composite utilizing the Clavien-Dindo Grading System for surgical complications. Attitudes toward office/virtual visits will be analyzed by comparing proportions of patients and providers who prefer a virtual visit, prefer an office visit, or have no preference.
    - All analyses will be conducted using an intention-to-treat principle. Baseline demographic and clinical characteristics will be summarized using descriptive statistics. Normally-distributed continuous measures will be summarized using mean and standard deviation (SD), whereas those showing departure from normality will be summarized using median and interquartile range (IQR). Categorical measures will be summarized using number of participants and percentage. The primary end-point analysis will be designed to test whether patient satisfaction with a virtual postoperative visit is noninferior to an in-person postoperative visit, as determined by the total PSQ-18 at the scheduled postoperative visit. Noninferiority would be shown if the lower limit of the two-sided 95% confidence interval for the between-group mean difference in the primary endpoint (i.e., the difference between the mean PSQ-18 total score in the virtual group minus the mean PSQ-18 total score in the in-office group) is more than -5 points. Similar analyses will be performed for each secondary outcome. The noninferiority margin is defined as 5 points for the PSQ-18 total score and 0.5 points for the PSQ-18 domain scores, 10% absolute for composite healthcare resource utilization, and 25% absolute for composite adverse events. Planned exploratory subgroup analyses of patient satisfaction, healthcare resource utilization and adverse events based on surgery level will be additionally performed.
    - All statistical analyses will be performed using JMP Pro version 17.0 software (SAS Institute, Cary, NC).
    - Data will be managed in REDCap. Statistical support will be provided by the Cleveland Clinic Quantitative Health Sciences.

E. **PRIVACY AND CONFIDENTIALITY**

Protection of each subject's personal health information will be a priority in this study. One master Excel file containing subject personal information including name and medical record number will be kept in a password-protected file, on a designated protected research drive on a password-protected computer in a locked office at the Cleveland Clinic. In that file, each subject will be assigned a subject identification number that will be used for the purposes of data collection in order to de-identify subjects. All paper forms used for data collection will be kept in a research cabinet dedicated to this project which will be locked at all times, in a

locked office at the Cleveland Clinic. All forms will contain de-identified information; identification numbers will correspond to the subjects listed in the master Excel file. All study data will be transferred and managed electronically using REDCap. Each subject will be entered into REDCap using the assigned identification number from the master Excel file.

F. DATA/SAMPLE SHARING

Not applicable

G. ADVERSE EVENTS AND DATA MONITORING

Any adverse event or unanticipated events will be reported as soon as feasible to the IRB using IRB WebKit. Examples of adverse events include inability to attend the postoperative visit due to technological issues (If the visit cannot be completed due to technological issues, the provider will ensure that the appointment is rescheduled to another time that is convenient and acceptable to the patient). All events will be recorded and kept in a research binder assigned to this study in a locked office. Monthly reviews during the study period will be done by all involved study staff members to ensure that events are not occurring, and if they are, that they are being handled and reported properly. The study will be terminated if patients in the intervention arm have decreased satisfaction of 20% compared to the control arm. This will be assessed monthly at the reviews mentioned above.

H. STUDY TIMELINE

The goal for this research study is for completion by the conclusion of the primary investigator's (LLL) three-year fellowship at Cleveland Clinic (June 2024). After obtaining institutional review board approval, a discussion will be held at the section research meeting to educate all urogynecology staff, fellows, and nurse practitioners on the implementation of this project. An in-service will be given to familiarize outpatient nursing staff and scheduling staff with the project.

Patient recruitment will begin thereafter with the goal of recruiting and completing data collection on all patients over an 18-month time period. At the end of this time, final data analysis will be performed and manuscript preparation will be initiated. The manuscript will be submitted to a high impact gynecology journal. This timeline ensures project completion well before the conclusion of the primary investigator's fellowship.

I. REFERENCES

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