ABSTRACT: The primary goal of vaginal reconstructive surgery is resolution of symptoms, thereby improving quality of life. For sexually active women, the first sexual encounters after surgery can be associated with pain, as well as fears of potential pain, discomfort, harming the repair or harming their partner. While patients often ask surgeons questions about resuming sexual activity, little is known about how to counsel patients about their first sexual encounter after vaginal reconstructive surgery.
Hypothesis: Use of a newly developed standardized counselling intervention regarding resumption of sexual activity will result in improved sexual function compared to routine care as measured on a validated sexual function questionnaire.
Objective: To determine if standardized counselling regarding first sexual encounter after vaginal reconstructive surgery for pelvic organ prolapse and / or urinary incontinence improves sexual function.
Aim 1: Develop a standardized tool for postoperative return to sexual activity based on prior qualitative work, an expert panel and cognitive interviews
Aim 2: Determine if postoperative standardized counselling for return to sexual activity after vaginal reconstructive surgery for pelvic organ prolapse and / or urinary incontinence results in better sexual function that regular counseling.

BACKGROUND: Pelvic organ prolapse is a common problem. A greater than 55% prevalence was noted in women age 50 to 59 years.[1] Population based studies report an 11 to 19 percent lifetime risk in women undergoing surgery for prolapse or incontinence.[2,3]

Though serious complications from vaginal pelvic organ prolapse surgery are relatively rare, new onset pain with sex and dyspareunia has been described. Antosh et al.[4], found in a systematic review that sexual function was unchanged or improved for most women but dyspareunia occurred at a rate of 0-9% after surgery. This systematic review highlighted that sexual function is often not a primary outcome of interest. Additionally, there is considerable movement between groups defined by sexual activity. This further limits reports of sexual function and sexual pain published thus far.

Caldwell et al.[5] presented a qualitative study of interviews of women of their first sexual encounter after POP surgery. The following major themes were identified: outside influences, conflicting emotions, sexual changes and stability, normalization and self-image.

STUDY DESIGN AND METHODS:
AIM #1: The first part of the study is the development of the standardized intervention for postoperative counselling on return to sexual activity. This will be based on previous qualitative work using the conceptual framework developed in that original study,[5]. An expert panel will be engaged to create a standardized counselling intervention through the Delphi process. After the instrument is created, we will use cognitive interviews of approximately 20 participants to ensure that the proposed standardized counselling intervention is clearly understood by women undergoing reconstructive surgery and that the meaning includes concepts identified in prior qualitative work. If problems are identified, the instrument will be revised by the expert panel and cognitive interviews will continue.
AIM #2: We will conduct a randomized controlled trial comparing standardized counseling to routine counseling regarding return to sexual activity using the instrument developed in AIM #1. Women who are undergoing reconstructive surgery for pelvic organ prolapse and / or urinary incontinence who report that they are sexually active will be eligible to participate. Our hypothesis is that use of a newly developed standardized counselling intervention regarding resumption of sexual activity will result in improved sexual function

as measured by a validated sexual function questionnaire compared to routine care. The primary outcome will be sexual function as measured by the PISQ-IR. In addition to the primary outcome, we will compare time to return to sexual activity, patient perception of their preparedness for return to sexual activity, and postoperative pain with sexual activity. Preparedness for return to sexual activity will be measured by modifying the Patient Preparedness Questionnaire, Question #11: "Overall, I feel prepared for my upcoming surgery" [6] We will consider women prepared if they answer "strongly agree" on a 5-point Likert scale from "strongly agree " to "strongly disagree" to the statement "Overall, I feel prepared for resuming sexual activity after my surgery". Pain with sexual activity will be assessed by response to question 11 on PISQ-IR "How often do you feel pain during sexual intercourse?"

Inclusion criteria: **consented for** vaginal reconstructive surgery for POP and / or UI, currently sexually active or not sexually active due to POP and / or UI but desiring of sexual activity

Exclusion Criteria: Not sexually AND not desiring of same.

Data Collection Timepoints:

- Pre-operative variables: Baseline demographics, menopausal status, vaginal estrogen use, PISQ-IR, POPQ, dyspareunia (superficial vs. deep), dyspareunia with penetrative movement, post-coital pain, hypertonic pelvic floor muscle, PFDI
- Intra-operative variables: type of procedure
- Post-operative 6-8 weeks variables: vaginal estrogen use (dose, frequency, form), POPQ, preparedness questionnaire PFDI
- Post-operative @ 4 months variables: menopausal status, vaginal estrogen use (dose, frequency, form), Vaginal dryness, Vaginal laxity questionnaire, PISQ-IR, new or same partner, dyspareunia (superficial vs. deep), dyspareunia with penetrative movement, post-coital pain, hypertonic pelvic floor muscle,

Sample size and Power:

For the first part, we anticipate recruiting 20 participants for the development of the intervention tool.

For the second part, a priori sample size calculation was performed. Our primary outcome will be total PISQ-IR score. There is no previously published work reporting minimally clinically important difference (MCID) with this questionnaire. However, we estimated the MCID as 1/2 standard deviation for baseline PISQ-IR scores from previously published work. Baseline PISQ-IR in similar patient population was 3.0 (SD 0.4).[7] A total of 128 patients would be required for analysis to provide 80% power to detect a treatment difference at a two-sided 0.05 significant level. However, based on previous work, 10% of women become sexually inactive between pre-operative and post-operative time points. We will also account for 20% loss to followup / dropout as we will be measuring outcomes at a time point remote for last clinical interaction. Therefore, we anticipate recruiting a total of 184 patients.

FEASIBILITY: Given the common clinical scenario vaginal reconstructive surgery for pelvic organ prolapse and urinary incontinence in this patient population, we anticipate adequate numbers of potential participants. Potential barriers include the time commitment for participants to complete the pre-operative and post-operative questionnaires, which will be planned for 30 minutes or less. There could be loss to followup due to length of time since last post-operative followup, however, this has been accounted for in the sample size calculation. There is potential for contamination or leakage of treatment intervention to the control group if individual surgeons have patients allocated to both groups.

BUDGET: Period of support: 24 months

Item	Cost	Total Cost
Data cleaning, management and analyst	$50 / hr x 40 hours	$2000 CAD
REDCAP or other electronic database	$250 / year / site x 6 sites	$3000 CAD
	TOTAL	$5000 CAD $3800 USD

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