Immediate Postoperative Pelvic Organ Prolapse Quantification Measures and 2-Year Risk of Prolapse Recurrence

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Abstract

Objective—To assess whether resting genital hiatus, perineal body, and total vaginal length measured intraoperatively at the conclusion of surgery are associated with prolapse recurrence 2-years after native-tissue pelvic organ prolapse reconstruction.

Methods—This ancillary analysis of the Operations and Pelvic Muscle Training in the Management of Apical Support Loss Trial included women who had an immediate post-op pelvic organ prolapse-quantification examination and 2-year follow-up. Primary outcome was bothersome bulge symptoms. Secondary outcomes were anatomic failure, surgical failure (either anatomic failure or bothersome bulge symptoms), and sexual function. Descriptive statistics assessed relationships between postprocedure Pelvic Organ Prolapse-Quantification measures and these four outcomes. Multivariable models were fit to the data to control for baseline differences in bivariate comparisons. Receiver operating characteristic curves were generated to identify an optimal genital hiatus cut-point associated with bothersome bulge, and this threshold was explored.

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[*]A list of NICHD Pelvic Floor Disorders Network members who contributed to the OPTIMAL study is available in Appendix 1 online at http://links.lww.com/xxx.

Results—This analysis included 368 participants. Bivariate analyses identified age, BMI, vaginal deliveries, baseline genital hiatus, perineal body, and advanced Pelvic Organ Prolapse-Quantification stage (3 vs. 2) as clinically relevant variables to include in multivariable models. After adjusting for these variables, the association between immediate post-op genital hiatus and bothersome bulge (adjusted odds ratio [AOR] 1.4; 95% CI 0.9, 2.1) was not significant at the p < 0.05 level; however immediate post-op genital hiatus was associated with anatomic (AOR 1.6; 95% CI 1.1, 2.3) and surgical failure (AOR 1.5; 95% CI 1.0, 2.1)Immediate post-op genital hiatus of 3.5 cm was the selected cutoff (AUC (95% CI) 0.58 (0.50, 0.66) from the bothersome bulge model). Women with genital hiatus 3.5 cm were more likely to have anatomic and surgical failures at 2 years. No Pelvic Organ Prolapse-Quantification measures were correlated with 2-year sexual function.

Conclusion—A larger immediate post-op genital hiatus measurement 3.5 cm is not associated with bothersome bulge symptoms or sexual dysfunction but is associated with anatomic and surgical failures 2 years after native tissue vaginal reconstructive surgery,.

Précis

Larger immediate postoperative genital hiatus (3.5 cm) is not associated with 2-year bothersome bulge symptoms or sexual dysfunction but is associated with anatomic and surgical failures after vaginal reconstruction.

Introduction

The goal of reconstructive surgery for pelvic organ prolapse is to limit the risk of prolapse recurrence while preserving vaginal length and caliber. Genital hiatus is measured in the Pelvic Organ Prolapse Quantification exam from the middle of the urethral meatus to the posterior hymenal ring. An enlarged genital hiatus has been associated with an increased severity of prolapse and recurrence following surgical repair. In non-surgical patients, larger baseline genital hiatus is associated with the increasing degrees of prolapse (1). In women undergoing surgery for prolapse, both enlarged preoperative genital hiatus (2, 3) and enlarged postoperative genital hiatus (1, 4) have been associated with prolapse recurrence. But there is little data regarding intraoperative genital hiatus or any guide to intraoperative assessment of vaginal dimensions following pelvic organ prolapse surgery. Surgeons commonly rely on digital exams or "gestalt" at the end of the procedure to judge the adequacy of their repair. Narrowing the genital hiatus has been advocated at the time of apical prolapse repair to reduce the risk of recurrent prolapse (2, 5) but must be balanced with efforts to preserve sexual function. Dyspareunia has not been shown to correlate directly to a change in vaginal dimensions after surgical correction of prolapse but is noted to be higher with certain procedures, such as posterior colporrhaphy.(6) The purpose of this study was to establish an objective, reproducible measure a surgeon could use to direct intraoperative decisions and potentially identify vaginal dimensions associated with surgical success without compromised sexual function at 2 years.

In the Operations and Pelvic Muscle Training in the Management of Apical Support Loss (OPTIMAL) Trial, all women undergoing native tissue vaginal apical prolapse repair, sacrospinous ligament fixation or uterosacral ligament suspension (7) had resting Pelvic

Organ Prolapse-Quantification measures of the genital hiatus, perineal body and total vaginal length, prospectively recorded at the conclusion of surgery. The primary aim of this ancillary analysis of the OPTIMAL trial was to examine the association of these immediate postoperative genital hiatus, perineal body and total vaginal length values and bothersome bulge symptoms 2-years after vaginal reconstruction surgery.

Methods

This was an unplanned ancillary analysis of the OPTIMAL Trial, conducted by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development Pelvic Floor Disorders Network (PFDN). Institutional review board approval was obtained at each of the 9 participating sites and all participants gave informed consent. Its design, methods, and results have been published previously (7, 8) Briefly, OPTIMAL (NCT 00597935) was a multi-center clinical trial conducted from 2008–2013 that randomized 374 women with symptomatic stage 2–4 pelvic organ prolapse and stress urinary incontinence in a 2×2 factorial design to sacrospinous ligament fixation (SSLF) or uterosacral vaginal vault ligament suspension (ULS), and to perioperative behavioral and pelvic floor muscle training or usual care. All participants had a planned midurethral sling. Postoperative anatomic and patient-reported outcomes were collected by study personnel blinded to both the surgical assignment and perioperative behavioral and pelvic floor muscle training. The primary aims of OPTIMAL were to assess the 24-month postoperative surgical prolapse outcomes and the impact of behavioral and pelvic floor muscle training on 6-month postoperative urinary symptoms as measured by the validated Pelvic Floor Distress Inventory. Surgical "success" was a composite outcome defined by the absence of (1) descent of the vaginal apex more than one-third of the total vaginal length; (2) anterior or posterior vaginal wall descent beyond the hymen; (3) bothersome bulge symptoms; and (4) retreatment for prolapse by either surgery or pessary. Using this composite definition, at 2 years, the surgical group assignment was not found to be significantly associated with the success rate, which was 64.5% for ULS and 63.1% for SSLF (adj OR 1.1; 95% CI 0.7 to 1.7) (7)

As part of OPTIMAL, a resting Pelvic Organ Prolapse-Quantification examination was performed by the primary surgeon at the conclusion of the procedure in the operating room. If a surgeon's assessment lead to revision, the only numbers captured were after all procedures were performed. These data recorded at the conclusion of surgery and analyzed here are the final examination numbers prior to leaving the operating room. This was primarily to ensure that all compartments were suspended at least 1 cm proximal to the hymen. While the effects of anesthesia and the lack of Valsalva are limitations to all measures except total vaginal length, these were the conditions under which the repairs were judged prior to leaving the operating room. The primary aim of this ancillary analysis of OPTIMAL was to determine if immediate postoperative genital hiatus, perineal body, or total vaginal length was associated with 24-month postoperative *bothersome bulge symptoms* defined by either retreatment for prolapse or an affirmative response to either of the two bulge-related questions of the Pelvic Floor Distress Inventory: (1) "Do you usually have a bulge or something falling out that you can see or feel in your vaginal area?"; and (2) "Do you usually have a sensation of bulging or protrusion from the vaginal area?" and a degree of bother of these symptoms described as "somewhat" or more. The Pelvic Floor

Distress Inventory is a validated symptom inventory that measures the degree of bother and distress caused by pelvic floor symptoms.

Secondary aims were to assess the relationships between these immediate postoperative Pelvic Organ Prolapse-Quantification values and *anatomic failure* (i.e., anterior or posterior prolapse beyond the hymen or apical decent more than one-third into the vagina canal or retreatment for prolapse) or *surgical failure* (i.e., either *anatomic failure* or bothersome bulge symptoms). While the OPTIMAL trial used surgical failure as the primary outcome, in this analysis, we were primarily interested in the subjective recurrence as reported by the patient. Therefore we chose to use *bothersome bulge symptoms* which represent both retreatment and recurrent symptoms that were bothersome but may not have led to retreatment. Anatomic failure and surgical failure were therefore included as secondary outcomes.

Finally, these Pelvic Organ Prolapse-Quantification measures were examined for associations with 24-month postoperative sexual function. Sexual function was assessed both by the Pelvic Organ Prolapse- Urinary Incontinence Sexual Questionnaire (PISQ-12) as well as responses to the additional question "Have you undergone any treatment for painful or difficult intercourse because your vagina was too narrow or too tight?" Details were collected as to whether surgery, dilators, physical therapy, trigger point injection, nortriptyline, or vaginal estrogen were employed for this indication. The PISQ-12 scores were calculated only for those patients who were sexually active within the 6 months prior to administration of the questionnaire, but the additional question regarding treatment for painful intercourse applied to all patients. Participants who had an immediate postoperative Pelvic Organ Prolapse-Quantification examination were eligible for analysis in this ancillary study.

Power estimates were based on the 303 OPTIMAL participants who had outcomes at 2 years, 300 of whom had a post-operative genital hiatus measurement. This sample size was estimated to provide over 80% power using a logistic regression model to detect an odds ratio of 1.4 for bothersome bulge symptoms for each standard deviation (0.7 cm) difference in immediate postoperative genital hiatus at a significance level of alpha = 0.05.

Statistical Analysis

Baseline characteristics of the analysis population were described as percentages or median and interquartile range. Characteristics were compared between those with and without outcomes at 2-years using Wilcoxon rank-sum tests for continuous measures, Mantel-Haenszel tests using modified-ridit scores for ordinal categorical measures, and Fisher's exact tests (expected cell count <5) or Chi-square tests for other categorical variables.

Immediate postoperative Pelvic Organ Prolapse-Quantification values were compared between those with and without bothersome vaginal bulge at 2-years using Wald tests from unadjusted logistic regression models. Similar bivariate analyses were conducted for other binary outcomes. Associations between immediate postoperative Pelvic Organ Prolapse-Quantification values and PISQ-12 scores were assessed using Spearman correlation and Fisher's transformation for 95% confidence intervals.

The relationships between immediate postoperative Pelvic Organ Prolapse-Quantification values (genital hiatus, perineal body, and total vaginal length) and bothersome vaginal bulge were assessed using unadjusted logistic regression and resulting receiver operating characteristic (ROC) curves. Area under the ROC curve (AUC) and 95% confidence interval (CI) was calculated to assess the ability of the Pelvic Organ Prolapse-Quantification measures to predict outcomes. The ROC curve and associated sensitivity and specificity values and 95% CI obtained via bootstrapping percentile method informed identification of the optimal postoperative genital hiatus cut-point for predicting bothersome bulge, and 2-year outcomes were compared between those above and below the cut-point using Wilcoxon rank-sum tests with Hodges-Lehmann estimation of location shift, Mantel-Haenszel tests using modified-ridit scores, and Fisher's exact tests (expected cell count <5) or Chi-square tests.

A logistic regression model was created to predict bothersome bulge based on immediate postoperative genital hiatus, controlling for baseline characteristics that were clinically important and statistically significant at the p<0.2 level in bivariate comparisons. Other binary secondary outcomes were analyzed similarly. Unless otherwise noted, statistical significance was assessed at the p<0.05 level, and no adjustments were made for multiple comparisons.

Results

This secondary analysis included 368 primarily white (84.2%) women with a median (minimum, maximum) age of 57 (29, 80) years and median (interquartile range) vaginal parity of 3 (2, 4). Detailed baseline demographics and clinical characteristics of participants are included in Table 1. Notably, 61.7% presented with Pelvic Organ Prolapse-Quantification stage 3 with 72.3% having anterior vaginal prolapse beyond the hymen. The median (minimum, maximum) genital hiatus at baseline was 4.5 (2.0, 10.0) cm. Participants with 2-year outcomes were comparable across all baseline demographics and clinical characteristics to those with missing outcomes (Appendix 2, available online at http://links.lww.com/xxx).

At 2 years follow-up, bothersome vaginal bulge symptoms were reported by 22% (64/291) of participants; 35.3% (106/300) met the study definition of overall surgical failure, and anatomic failure was recorded in 24.2% (76/314). Surgical or pessary retreatment for recurrent prolapse was reported by 5.1% (16/314). Nine women (2.5%) reported treatment to address painful sexual intercourse including vaginal dilators (2), pelvic floor physical therapy (3), vaginal estrogen (2), trigger point injections (1), and nortriptyline (1).

In unadjusted analysis, immediate post-op genital hiatus was associated with subsequent development of bothersome bulge symptoms, anatomic and surgical failures at 2-years after surgery but was not associated with pelvic organ prolapse re-treatment. Symptomatic participants and those meeting criteria for anatomic and surgical failures had a larger mean genital hiatus (mean 3.5cm for bothersome bulge and surgical failure, 3.6cm for anatomic failure) compared to the mean genital hiatus of 3.3 cm in those without these undesirable outcomes (Table 2). Immediate post-op Pelvic Organ Prolapse-Quantification measures

perineal body and total vaginal length were not associated with any of the prolapse outcomes.

The multivariable models were adjusted for variables found to have a clinically relevant difference between those with and without the prolapse outcomes. Vaginal deliveries, baseline genital hiatus, baseline perineal body, and advanced Pelvic Organ Prolapse-Quantification stage (3 vs. 2) were included in models to predict bothersome bulge, surgical failure, and anatomic failure. Additionally, BMI and age were included in the models for bothersome bulge symptoms and anatomic failure respectively. After adjusting for these variables, the association between immediate post-op genital hiatus and bothersome bulge (adjusted odds ratio [AOR] 1.4; 95% CI 0.9, 2.1) was not significant at the $p < 0.05$ level; however immediate post-op genital hiatus remained associated with anatomic (AOR 1.6; 95% CI 1.1, 2.3) and surgical failure (AOR 1.5; 95% CI 1.0, 2.1). In these models, larger baseline perineal body and higher baseline Pelvic Organ Prolapse-Quantification stage were also independently associated with anatomic (perineal body AOR 1.5; 95% CI 1.1, 2.0; Pelvic Organ Prolapse-Quantification Stage 3 AOR 3.3; 95% CI 1.6, 6.9) and surgical failures (perineal body AOR 1.5; 95% CI 1.1, 1.9 and Pelvic Organ Prolapse-Quantification Stage 3 AOR 1.8; 95% CI 1.0, 3.2) but not bothersome bulge (perineal body AOR 1.3; 95% CI 1.0, 1.7 and Pelvic Organ Prolapse-Quantification Stage 3 AOR 1.4; 95% CI 0.7, 2.6).

ROC curves from unadjusted logistic regression models indicated a weak ability of post-operative genital hiatus to predict bothersome bulge (AUC 0.58; 95% CI 0.50, 0.66) and surgical failure (AUC 0.59; 95% CI 0.53, 0.66) (Fig. 1). Immediate post-operative genital hiatus of 3.5 cm was selected as the threshold cutoff. This cutoff was selected as it represented a point at which sensitivity and specificity were maximized and both >50% for both outcomes (Appendix 3, available online at http://links.lww.com/xxx). Testing of this threshold indicated that women with genital hiatus < 3.5 cm compared to those with genital hiatus 3.5 cm were less likely to have any vaginal bulge symptoms (19.5% vs. 29.5%; OR 0.6; 95% CI 0.3, 1.0, anatomic failure (17.0% vs. 32.2%; OR 0.4; 95% CI 0.3, 0.7) and surgical failure (27.3% vs. 44.6%; OR 0.5; 95% CI 0.3, 0.8) at 2-years (Table 3). Furthermore, in women with genital hiatus < 3.5 cm, prolapse beyond the hymen was less likely in the anterior (8.5% vs. 17.5%; OR 0.4; 95% CI 0.2, 0.9), posterior (0.6% vs. 4.9%; OR 0.1; 95% CI 0.0, 1.0), and apical (0.0% vs. 2.8%; OR 0.0; 95% CI 0.0, 1.0) compartments.

Immediate post-op genital hiatus and total vaginal length measures were not correlated with 2-year sexual function PISQ-12 scores or associated with 2-year treatment for painful sexual intercourse (Table 2). Immediate post-op perineal body had a weak but significant correlation with PISQ-12 score but was not associated with treatment for painful sexual intercourse.

Of note, in this analysis, if a posterior colporrhaphy was performed, the median immediate postoperative genital hiatus was 3.0 cm, and 61.7% had genital hiatus <3.5 cm. If no posterior colporrhaphy was performed, the median genital hiatus was 3.5 cm but still 43.9% had genital hiatus <3.5 cm.

Discussion

In this secondary analysis of a large multi-center clinical trial comparing outcomes of two native-tissue apical suspension procedures, larger genital hiatus (3.5 cm) measured at the completion of the surgery, at rest, under anesthesia, was not associated with bothersome bulge symptoms but was associated with anatomic and surgical failure 2-years after prolapse surgery. In contrast, immediate postoperative measurements of the perineal body or total vaginal length were not associated with these 2-year outcomes. Similarly, the genital hiatus, perineal body and total vaginal length measured immediately postoperatively had no relationship with postoperative sexual function as measured by a validated patient-reported sexual function measure or treatment for painful sexual intercourse.

These findings regarding larger immediate postoperative genital hiatus size (3.5 cm) are consistent with previous studies. Genital hiatus size has been shown to be larger, on average, in patients with pelvic organ prolapse than those without. In a cross-sectional study of 300 women (matched for age and parity) Delancey and Hurd found that in women with normal support and no prior surgery, mean hiatus area was 5.4+/− 1.71 cm^2. In uncorrected prolapse (Baden-Walker grade 2–3), hiatus area was 9.6 +/− 3.97 cm^2 and became larger with progressive prolapse. (1) The authors also noted that the area of the genital hiatus was larger in women who had several failed surgeries as compared to those who underwent successful surgery and even those who had a single failed surgery. (1) Additionally, preoperative genital hiatus has been associated with recurrent prolapse after surgery (2, 5) and is an important independent predictor of surgical failure in a recently published risk prediction calculator for women with pelvic organ prolapse contemplating surgery. (9) Lowder et. al also identified a threshold measurement, where preoperative genital hiatus 3.75 cm was highly predictive of apical support loss. (3) Recently, two studies reported that patients with pre-operative genital hiatus >4 cm who continued to demonstrate an enlarged genital hiatus >4 cm at 6 weeks after surgery had an increased odds of surgical failure after both vaginal native-tissue vaginal robotic-assisted prolapse repairs (4, 10).

What is unique about our analysis compared to those cited, is that it evaluated the association between 2-year surgical outcomes and the genital hiatus measurement upon completion of the surgery while the patient was under anesthesia, and when the surgeon had the opportunity to supplement the apical suspension repair. We found that a larger genital hiatus under these circumstances was associated with 2-year surgical outcomes. Moreover, our data suggest that 3.5 cm genital hiatus length represents a potentially important threshold for surgeons. Reconstructive pelvic surgeons often consider narrowing an enlarged genital hiatus, by perineorrhaphy or other approaches, to decrease postoperative vaginal bulge symptoms and anatomic recurrence while avoiding introital narrowing that might lead to sexual dysfunction. In the absence of precise measurement, historically, surgeons have judged introital caliber by digital examination at the end of the procedure, often using 2–3 fingerbreadths in width as a goal. (11, 12) The results of this study suggest surgeons may improve surgical outcomes by using precise and reproducible Pelvic Organ Prolapse-Quantification measures of genital hiatus, rather than the "gestalt" assessments to guide their intraoperative decision to restrict the genital hiatus. We acknowledge that immediate postoperative genital hiatus measurement and its relationship with 2-year outcomes may

reflect, at least in part, preoperative genital hiatus or overall severity of pelvic floor function or vaginal support loss rather than just a surgical result that is wholly modifiable. The relationship between genital hiatus size and prolapse is likely bidirectional; deficient connective tissue support of the outlet likely compromises the basal support of the vagina and perineum, hypothetically exposing more internal structures to greater physiologic stresses. Conversely, genital hiatus as measured during strain in a patient with prolapse, is at least to some degree driven by the tissues prolapsing through it, and thus distending these structures and influencing the measurement.

Sutkin et al recently reported a secondary analysis of the OPTIMAL trial comparing the results of 190 participants who received a posterior colporrhaphy to 184 participants who did not and found no association between posterior repairs and long-term surgical success both before and after adjusting for baseline covariates using a propensity score approach.(13) Importantly, in the OPTIMAL trial, posterior colporrhaphy was performed at the discretion of the surgeon. The only guidance about whether or not a posterior colporrhaphy should be performed was that the posterior vaginal wall needed to be supported   1cm proximal to the hymen. Therefore, there was high variation in the performance of posterior repair by surgeon [15–79%]. Moreover, there was no standardization of technique or recording of methods to narrow the introitus separately from those procedures intended to only correct posterior vaginal wall prolapse. The analysis of Sutkin et al does, however, provide some reason for caution before we conclude that a strategy of performing a posterior colporrhaphy or perineorrhaphy in those women whose immediate postoperative genital hiatus is enlarged will necessarily improve long-term outcomes. One can imagine it is possible to have a genital hiatus <3.5 cm without posterior colporrhaphy. It is also possible to perform a posterior colporrhaphy without narrowing genital hiatus to <3.5 cm. In this analysis, if a posterior colporrhaphy was performed, 61.7% had genital hiatus <3.5 cm but 38.3% had genital hiatus   3.5 cm. Those who did not have a posterior colporrhaphy performed, 56.1% had genital hiatus   3.5 cm but still 43.9% had genital hiatus <3.5 cm. In a recent study, Carter-Brooks et al. found that women with a larger preoperative genital hiatus were more likely to receive a posterior repair resulting in larger reduction in genital hiatus. (14) However, a smaller preoperative genital hiatus length was associated with surgical success regardless of the performance of a posterior repair in this study. Future studies evaluating a strategy of introital narrowing should, therefore, use a standardized threshold genital hiatus size (such as   3.5 cm after performance of any apical suspension) and a standardized surgical approach to reduce the genital hiatus and prospectively compare the outcomes of this approach to a control group where no such narrowing occurs. At minimum, the current analysis provides important data to study such an approach.

The current analysis confirms prior studies that show little relationship between vaginal dimensions after prolapse surgery and postoperative sexual function. (6, 11, 15–20) Although vaginal shortening is typical after prolapse surgery, these prior studies demonstrate that postoperative Pelvic Organ Prolapse-Quantification values, including genital hiatus, perineal body and total vaginal length, have little or no correlation with dyspareunia or sexual functioning. Our analysis suggests that this also is true for immediate postoperative assessments of these Pelvic Organ Prolapse-Quantification values. Importantly, these Pelvic Organ Prolapse-Quantification measurements are relatively crude assessments of the vaginal

or pelvic anatomy and may not account for mid-vaginal constrictions, pelvic muscle dysfunction or other factors that can result from surgery. Sexual function is multi-dimensional and, in general, improves after pelvic organ prolapse surgery with a minority of patients developing new onset dyspareunia or dysfunction suggesting vaginal dimensions play only a minor role. (6, 11, 14–19)

Strengths of our analysis include using data from a robust multi-center clinical trial of pelvic organ prolapse surgery that used validated measures of anatomic and functional outcomes that also assessed vaginal anatomy using Pelvic Organ Prolapse-Quantification immediately after completion of surgery. A potential limitation is that primary surgeon obtained immediate postop Pelvic Organ Prolapse Quantification measures were while the patient was under anesthesia without straining, however these are reproducible real-world conditions for surgeons evaluating the anatomic results of their repair leaving the operating room and present a rare opportunity to modify the repair intraoperatively. In contrast to those cited references, this study uniquely evaluated immediate postoperative anatomy using the Pelvic Organ Prolapse-Quantification examination and its impact on long-term surgical outcome.

In conclusion, this analysis suggests that genital hiatus measured immediately after completion of pelvic organ prolapse surgery while still under anesthesia is associated with 2-year anatomic and composite surgical success but not bothersome bulge symptoms or sexual function, after native tissue apical suspension procedures. An immediate postoperative genital hiatus of 3.5 cm or greater may be predictive of recurrent prolapse. Confirmation of our finding through further study has the potential to inform surgeons intraoperatively on the potential benefit of adjuvant posterior repair with the goal of improving surgical outcomes.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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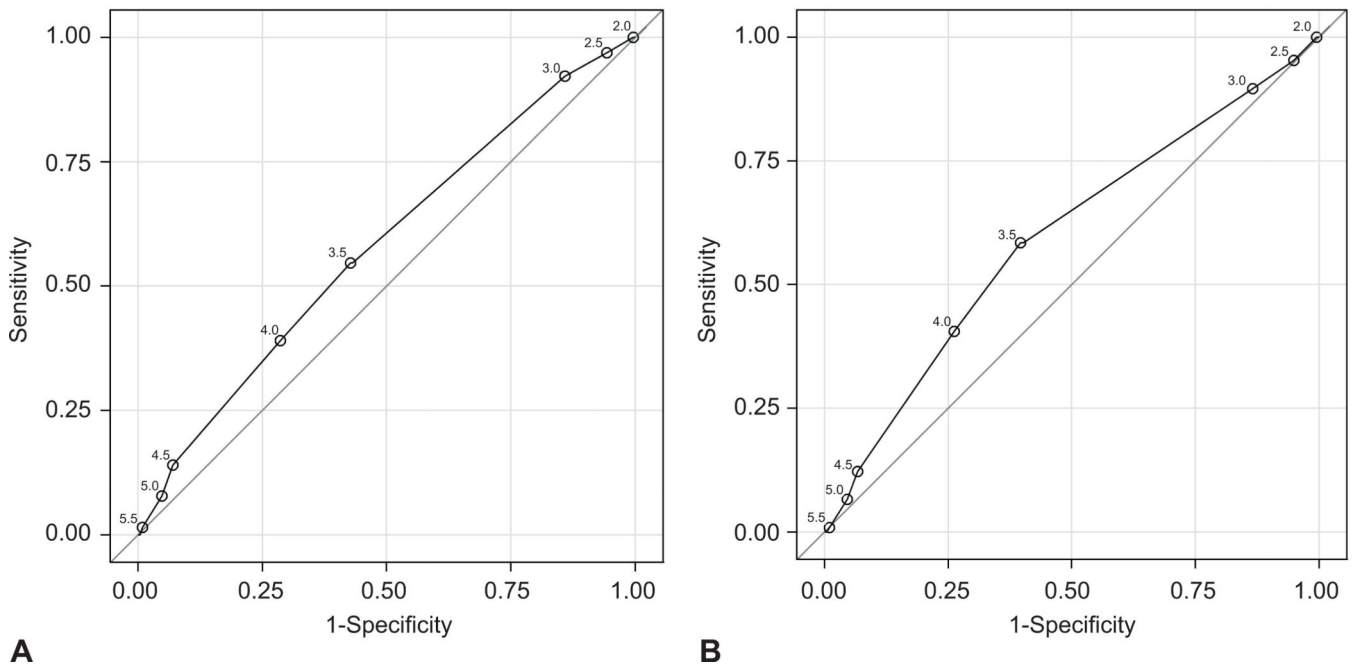
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B

Figure 1:
Receiver operator curves (ROC)* predicting bothersome vaginal bulge (**A**)[†] and surgical failure (**B**)[‡] at 24 months by immediate postoperative pelvic organ prolapse-quantification (POP-Q) genital hiatus in the analysis population.[§] **A.** Area under the curve (95% CI): 0.59 (0.53, 0.66). **B.** Area under the curve (95% CI): 0.58 (0.50, 0.66).*The predicted probabilities, sensitivity, specificity, area under the curve and 95% CI for the ROC are obtained from logistic regression models for bothersome vaginal bulge at 24 months and surgical failure at 24 months predicted based on immediate postoperative POP-Q point genital hiatus. [†]Bothersome vaginal bulge is defined as a positive response at the visit of interest if one of the following criteria is met: a positive response to bothersome vaginal bulge symptoms or retreatment for pelvic organ prolapse (POP) through the visit of interest. Bothersome vaginal bulge symptoms is defined as a positive response at the visit of interest to any vaginal bulge symptoms and a response of somewhat, moderately, or quite a bit to the follow-up question, "How much does this bother you?" to either item 4 or 5 on PFDI. Any vaginal bulge symptoms is defined as a positive response at the visit of interest to either item 4 on the Pelvic Floor Distress Inventory (PFDI), "Do you usually have a sensation of bulging or protrusion from the vaginal area?" or item 5 on PFDI "Do you usually have a bulge or something falling out that you can see or feel in the vaginal area?" [‡]Surgical failure at 24 months is defined as not meeting all of the following criteria: POP-Q value C −2/3 x total vaginal length at 24 months, all POP-Q values of points Aa, Ba, Ap, and Bp 0 at 24 months, experiencing no bothersome vaginal bulge symptoms at 24 months, and no retreatment for pelvic organ prolapse (POP). Retreatment for POP is defined as reoperation or pessary for POP through 24 months after surgery. [§]The analysis population includes all participants that were eligible, gave consent, were randomized to both the pelvic muscle training and surgical interventions, and had immediate postoperative POP-Q measurements.

Only participants for whom the outcome was assessed (ie. nonmissing) are included in the analysis.

Table 1.

Demographics and Baseline Clinical Characteristics in the Analysis Population [†]

Characteristic	N	n (%) [*]
Age (years), Median (Min, Max)	368	57 (29, 80)
Race	368	
White		310 (84.2)
African American		21 (5.7)
Other		37 (10.1)
No. of Vaginal Deliveries, Median (P25, P75)	368	3 (2, 4)
No. of Cesarean Deliveries	368	
0		336 (91.3)
1		32 (8.7)
Menstrual Status	347	
Pre-Menopausal		102 (29.4)
Post-Menopausal		245 (70.6)
Body Mass Index (kg/m^2), Median (P25, P75)	367	28 (25, 32)
Prior Procedures		
Hysterectomy		100 (27.2)
Stress Urinary Incontinence Surgery		13 (3.5)
Pelvic Organ Prolapse Surgery		25 (6.8)
POPQ Stages [‡]	368	
Stage 2		141 (38.3)
Stage 3		227 (61.7)
POPQ Values [§] (cm), Median (Min, Max)		
Aa	368	1.0 (−3.0, 3.0)
Ba	368	2.0 (−3.0, 11.0)
C	367	−2.0 (−6.0, 11.0)
Ap	368	−1.0 (−3.0, 3.0)
Bp	368	−1.0 (−3.0, 11.0)
GH	367	4.5 (2.0, 10.0)
PB	367	3.0 (0.0, 7.0)
TVL	368	9.5 (3.0, 12.0)
Bothersome Vaginal Bulge Symptoms [‖]	348	325 (93.4)
Prolapse beyond the hymen		
Anterior (POPQ Aa or Ba > 0)	368	266 (72.3)
Posterior (POPQ Ap or Bp > 0)	368	72 (19.6)
Apical (POPQ C > 0)	367	111 (30.2)
Apical Descent (C > −2/3 TVL)	367	359 (97.8)

Characteristic	N	n (%) [*]
PISQ 12 Score, Median (P25, P75)	179	31 (26, 37)
Posterior Colporrhaphy Performed	368	188 (51.1)

[*]
Data shown are n (%), unless otherwise specified. P25=25th Percentile, P75=75th Percentile.

[†]The analysis population includes all participants that were eligible, gave consent, were randomized to both the PMT and surgical interventions, and had immediate post-operative POPQ measurements.

[‡]Pelvic Organ Prolapse Quantification (POPQ) Stages: Stage 2-The vagina is prolapsed between 1 cm above the hymen and 1 cm below the hymen; Stage 3-The vagina is prolapsed more than 1 cm beyond the hymen but is less than totally everted; Stage 4-The vagina is everted to within 2 cm of its length.

[§]In the POPQ system, the positions of C, Ba and Bp are measured at the most dependent location (the point of greatest prolapse) of the apex, anterior vaginal wall and posterior vaginal wall respectively during a straining. Values are measured in cm and are negative if above the hymen, and positive if below the hymen. TVL (total vaginal length), GH (genital hiatus) and PB (perineal body) are measured as positive values.

[‖]Bothersome vaginal bulge symptoms is defined as a positive response at the visit of interest to any vaginal bulge symptoms and a response of "Somewhat", "Moderately", or "Quite a Bit" to the follow-up question "How much does this bother you?" to either item 4 or 5 on PFDI. Any vaginal bulge symptoms is defined as a positive response at the visit of interest to either item 4 on PFDI "Do you usually have a sensation of bulging or protrusion from the vaginal area?" or item 5 on PFDI "Do you usually have a bulge or something falling out that you can see or feel in the vaginal area?"

Table 2.

Primary and Secondary Outcomes Association with Immediate Post-Operative POP-Q GH, PB, and TVL in the Analysis Population [*] (Unadjusted)

Outcome at 2 years	Immediate Post-Op POPQ GH		Immediate Post-Op POPQ PB		Immediate Post-Op POPQ TVL	
	N=368	P-value [†]	N=367	P-value [†]	N=368	P-value [†]
Primary Outcome						
Bothersome Vaginal Bulge [‡]						
Yes, n/N (%)	64/291 (22.0)		63/290 (21.7)		64/291 (22.0)	
Mean (SD)	3.5±0.7		3.7±0.9		8.3±1.0	
No, n/N (%)	227/291 (78.0)		227/290 (78.3)		227/291 (78.0)	
Mean (SD)	3.3±0.7		3.7±0.9		8.3±1.3	
Odds Ratio (95% CI) for Predicting Bothersome Vaginal Bulge	1.5 (1.0 – 2.2)	**0.042**	1.0 (0.8 – 1.4)	0.780	1.0 (0.8 – 1.2)	0.765
Secondary Outcomes						
Surgical Failure [§]						
Yes, n/N (%)	106/300 (35.3)		105/299 (35.1)		106/300 (35.3)	
Mean (SD)	3.5±0.7		3.8±0.9		8.2±0.9	
No, n/N (%)	194/300 (64.7)		194/299 (64.9)		194/300 (64.7)	
Mean (SD)	3.3±0.7		3.6±0.9		8.3±1.3	
Odds Ratio (95% CI) for Predicting Surgical Failure	1.5 (1.1 – 2.1)	**0.012**	1.2 (0.9 – 1.5)	0.212	0.9 (0.8 – 1.1)	0.542
Anatomic Failure [‖]						
Yes, n/N (%)	76/314 (24.2)		75/313 (24.0)		76/314 (24.2)	
Mean (SD)	3.6±0.8		3.8±0.9		8.2±1.0	
No, n/N (%)	238/314 (75.8)		238/313 (76.0)		238/314 (75.8)	
Mean (SD)	3.3±0.7		3.6±0.9		8.3±1.2	
Odds Ratio (95% CI) for Predicting Anatomic Failure	1.6 (1.2 – 2.3)	**0.006**	1.2 (0.9 – 1.6)	0.190	0.9 (0.7 – 1.1)	0.215
Pelvic Organ Prolapse Retreatment [¶]						
Yes, n/N (%)	16/314 (5.1)		15/313 (4.8)		16/314 (5.1)	
Mean (SD)	3.6±0.9		3.7±1.2		8.0±1.1	
No, n/N (%)	298/314 (94.9)		298/313 (95.2)		298/314 (94.9)	
Mean (SD)	3.4±0.7		3.7±0.9		8.3±1.2	
Odds Ratio (95% CI) Predicting Pelvic Organ Prolapse Retreatment [6]	1.5 (0.8 – 2.8)	0.241	1.0 (0.6 – 1.8)	0.928	0.8 (0.6 – 1.2)	0.298
Painful Sexual Intercourse Treatment [#]		0.577		0.795		0.665
Yes, n/N (%)	9/361 (2.5)		9/360 (2.5)		9/361 (2.5)	
Mean (SD)	3.3±0.6		3.7±0.8		8.2±1.0	
No, n/N (%)	352/361 (97.5)		351/360 (97.5)		352/361 (97.5)	

Outcome at 2 years	Immediate Post-Op POPQ GH		Immediate Post-Op POPQ PB		Immediate Post-Op POPQ TVL	
	N=368	P-value †	N=367	P-value †	N=368	P-value †
Mean (SD)	3.4±0.8		3.6±0.9		8.3±1.2	
Odds Ratio (95% CI) Predicting Painful Sexual Intercourse Treatment [7]	0.8 (0.3 – 1.9)	0.577	1.1 (0.5 – 2.3)	0.795	0.9 (0.5 – 1.5)	0.665
PISQ 12 Score Correlation (95% CI)	−0.04 (−0.20 – 0.11)	0.571	−0.17 (−0.32 – −0.02)	**0.026**	0.10 (−0.06 – 0.25)	0.208

*
The analysis population includes all participants that were eligible, gave consent, were randomized to both the PMT and surgical interventions, and had immediate post-operative POPQ measurements. Only participants for whom the outcome was assessed (i.e. non-missing) are included in the analysis.

†
Unadjusted odds ratios for predicting each outcome based on immediate POPQ measure (GH, PB, or TVL), 95% confidence intervals, and p-values were obtained from the Wald test from unadjusted logistic regression models. Odds ratios are for a one-unit increase in the immediate POPQ measure. P-values and 95% confidence intervals for correlation with PISQ 12 score were obtained using the non-parametric Spearman rank correlation test and Fisher's transformation respectively. Bold text indicates p values < 0.05.

‡
Bothersome vaginal bulge is defined as a positive response at the visit of interest if one of the following criteria is met: a positive response to bothersome vaginal bulge symptoms or retreatment for pelvic organ prolapse (POP) through the visit of interest. Bothersome vaginal bulge symptoms is defined as a positive response at the visit of interest to any vaginal bulge symptoms and a response of "Somewhat", "Moderately", or "Quite a Bit" to the follow-up question "How much does this bother you?" to either item 4 or 5 on PFDI. Any vaginal bulge symptoms is defined as a positive response at the visit of interest to either item 4 on PFDI "Do you usually have a sensation of bulging or protrusion from the vaginal area?" or item 5 on PFDI "Do you usually have a bulge or something falling out that you can see or feel in the vaginal area?"

§
Surgical failure at 24 months is defined as not meeting all of the following criteria: POPQ value C   −2/3 × TVL at 24 months, all POPQ values of points Aa, Ba, Ap, and Bp   0 at 24 months, experiencing no bothersome vaginal bulge symptoms at 24 months, and no retreatment for pelvic organ prolapse (POP).

‖
Anatomic failure is defined as meeting any of the following at the visit of interest: POPQ C > −2/3 × TVL, any of POPQ points Aa, Ba, Ap, and Bp > 0, or retreatment for pelvic organ prolapse (POP).

¶
Retreatment for pelvic organ prolapse (POP) is defined as re-operation or pessary for POP through 24 months post-surgery.

#
Treatment for painful sexual intercourse due to a narrow or tight vagina includes surgery (n=0), vaginal dilators (n=2), physical therapy (n=3), vaginal estrogen (n=2), trigger point injection (n=1), or nortriptyline (n=1) through 24 months post-surgery.

Table 3.

Primary and Secondary Outcomes at 2 years for Participants < or ≥ the Threshold [†] for Immediate Post-Operative GH in the Analysis Population [‡]

Outcome at 2 years	Immediate Post-Operative GH < 3.5 (N=195)		Immediate Post-Operative GH ≥ 3.5 (N=173)		OR/Location Shift (95% CI) [§]	P-value [§]
	n (%) [*]	N	n (%) [*]	N		
Primary Outcome						
Bothersome Vaginal Bulge	29 (18.2)	159	35 (26.5)	132	0.6 (0.4 – 1.1)	0.090
Secondary Outcomes						
Surgical Failure [¶]	44 (27.3)	161	62 (44.6)	139	0.5 (0.3 – 0.8)	**0.002**
Pelvic Organ Prolapse Retreatment [#]	7 (4.2)	167	9 (6.1)	147	0.7 (0.2 – 1.8)	0.438
Any Vaginal Bulge Symptoms [**]	31 (19.5)	159	39 (29.5)	132	0.6 (0.3 – 1.0)	**0.046**
Anatomic Failure [††]	28 (17.0)	165	48 (32.2)	149	0.4 (0.3 – 0.7)	**0.002**
Apical Descent (C > –2/3 TVL)	13 (8.0)	163	23 (16.1)	143	0.5 (0.2 – 0.9)	**0.028**
Prolapse beyond the hymen						
Anterior (POPQ Aa or Ba > 0)	14 (8.5)	164	25 (17.5)	143	0.4 (0.2 – 0.9)	**0.019**
Posterior (POPQ Ap or Bp > 0)	1 (0.6)	164	7 (4.9)	143	0.1 (0.0 – 1.0)	**0.027**
Apical (POPQ C > 0)	0 (0.0)	163	4 (2.8)	143	0.0 (0.0 – 1.0)	**0.047**
POPQ Stages [‡‡]		164		143		0.075
Stage 0	8 (4.9)		5 (3.5)		Reference	
Stage 1	56 (34.1)		32 (22.4)		1.1 (0.3 – 4.2)	
Stage 2	93 (56.7)		92 (64.3)		0.6 (0.2 – 2.3)	
Stage ≥ 3	7 (4.3)		14 (9.8)		0.3 (0.1 – 1.6)	
POPQ Values [a] (cm), Median (P25, P75)						
GH	3.0 (2.5, 4.0)	164	4.0 (3.0, 4.0)	143	–0.5 (–1.0 – 0.0)	**<0.001**
PB	4.0 (3.0, 4.0)	164	3.0 (3.0, 4.0)	143	0.0 (0.0 – 0.5)	**0.005**
TVL	8.0 (7.0, 9.0)	164	8.0 (7.0, 9.0)	143	0.0 (0.0 – 0.5)	0.092
PISQ 12 Score, Median (P25, P75)	38 (31, 42)	90	36 (31, 40)	72	1.0 (–2.0 – 3.0)	0.579
Painful Sexual Intercourse Treatment [b]	7 (3.6)	192	2 (1.2)	169	3.2 (0.6 – 31.5)	0.182

[*] Data shown are n (%), unless otherwise specified. P25=25th Percentile, P75=75th Percentile.

[†] The post-operative POPQ GH threshold of 3.5 was identified based on the ROC Curve (Figure 1).

[‡] The analysis population includes all participants that were eligible, gave consent, were randomized to both the PMT and surgical interventions, and had immediate post-operative POPQ measurements. Only participants for whom the outcome was assessed (i.e. non-missing) are included in the analysis.

[§]Unadjusted location shift, 95% confidence intervals, and p-values were obtained using Wilcoxon Rank-Sum test for continuous measures with a Hodges-Lehmann estimation of location shift. Unadjusted odds ratios, 95% confidence interval, and p-values were obtained using Chi-Squared test or Fisher's exact test (expected cell count <5) for nominal categorical measures. P-values for ordinal categorical measures were obtained using Mantel-Haenszel test using modified ridit scores and pairwise unadjusted odds ratios and 95% confidence intervals were obtained from Fisher's exact test. Bold text indicates p values < 0.05.

[∥]Bothersome vaginal bulge is defined as a positive response at the visit of interest if one of the following criteria is met: a positive response to bothersome vaginal bulge symptoms or retreatment for pelvic organ prolapse (POP) through the visit of interest. Bothersome vaginal bulge symptoms is defined as a positive response at the visit of interest to any vaginal bulge symptoms and a response of "Somewhat", "Moderately", or "Quite a Bit" to the follow-up question "How much does this bother you?" to either item 4 or 5 on PFDI. Any vaginal bulge symptoms is defined as a positive response at the visit of interest to either item 4 on PFDI "Do you usually have a sensation of bulging or protrusion from the vaginal area?" or item 5 on PFDI "Do you usually have a bulge or something falling out that you can see or feel in the vaginal area?"

[¶]Surgical failure at 24 months is defined as not meeting all of the following criteria: POPQ value C ≤ −2/3 × TVL at 24 months, all POPQ values of points Aa, Ba, Ap, and Bp ≤ 0 at 24 months, experiencing no bothersome vaginal bulge symptoms at 24 months, and no retreatment for pelvic organ prolapse (POP).

[#]Retreatment for pelvic organ prolapse (POP) is defined as re-operation or pessary for POP through 24 months post-surgery.

[**]Any vaginal bulge is defined as a positive response at the visit of interest if one of the following criteria is met: a positive response to any vaginal bulge symptoms or retreatment for pelvic organ prolapse (POP) through the visit of interest. Any vaginal bulge symptoms is defined as a positive response at the visit of interest to either item 4 on PFDI "Do you usually have a sensation of bulging or protrusion from the vaginal area?" or item 5 on PFDI "Do you usually have a bulge or something falling out that you can see or feel in the vaginal area?"

[††]Anatomic failure is defined as meeting any of the following at the visit of interest: POPQ C > −2/3 × TVL, any of POPQ points Aa, Ba, Ap, and Bp > 0, or retreatment for pelvic organ prolapse (POP).

[‡‡]Pelvic Organ Prolapse Quantification (POPQ) Stages: Stage 0-The vagina is not prolapsed; Stage 1-The vagina is prolapsed more than 1 cm above the hymen; Stage 2-The vagina is prolapsed between 1 cm above the hymen and 1 cm below the hymen; Stage 3-The vagina is prolapsed more than 1 cm beyond the hymen but is less than totally everted; Stage 4-The vagina is everted to within 2 cm of its length.

[a]In the POPQ system, the positions of C, Ba and Bp are measured at the most dependent location (the point of greatest prolapse) of the apex, anterior vaginal wall and posterior vaginal wall respectively during a straining. Values are measured in cm and are negative if above the hymen, and positive if below the hymen. TVL (total vaginal length), GH (genital hiatus) and PB (perineal body) are measured as positive values.

[b]Treatment for painful sexual intercourse due to a narrow or tight vagina includes surgery (n=0), vaginal dilators (n=2), physical therapy (n=3), vaginal estrogen (n=2), trigger point injection (n=1), or nortriptyline (n=1) through 24 months post-surgery.