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Open Sacrocolpopexy and vaginal apical repair: Retrospective comparison of success and serious complications

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Abstract

Introduction and hypothesis—To compare treatment success and adverse events between women undergoing open sacrocolpopexy (ASC) versus vaginal repair (VAR) using data from women enrolled in one of three multicenter trials. We hypothesized that ASC would result in better outcomes than VAR.

Methods—Participants underwent apical repair of stage 2–4 prolapse. Vaginal repair included uterosacral, sacrospinous, and ilioococcygeal suspensions; sacrocolpopexies were via laparotomy. Success was defined as no bothersome bulge symptoms, no prolapse beyond the hymen and no retreatment up to 24 months. Adverse events were collected at multiple time-points. Outcomes were analyzed using longitudinal mixed effects models to obtain valid outcome estimates at specific visit times, accounting for data missing at random. Comparisons were controlled for center, age, BMI, initial POPQ stage, baseline scores, prior prolapse repair and concurrent repairs.

Results—Of women who met inclusion criteria (1022 women included /1159 eligible); 701 underwent vaginal repair. The sacrocolpopexy group (n=321) was older, more likely White, had prior prolapse repairs, and Stage 4 prolapse (all $p<0.05$). While POPQ measurements and symptoms improved in both groups, treatment success was higher in the sacrocolpopexy group (OR:6.00, 95% CI:3.45–10.44). The groups did not differ significantly in most questionnaire responses at 12 months and overall bowel and bladder function improvement. By 24 months, fewer patients had undergone retreatment (2% sacrocolpopexy vs 5% vaginal repair); serious adverse events did not differ significantly through 6 weeks (13% vs 5%, OR:2.0, 95% CI:0.9–4.7) and 12 months (26% vs 13%, OR:1.6, 95% CI:0.9–2.9) respectively.

Conclusions—Open sacrocolpopexy resulted in more successful prolapse treatment at 2 years.

Keywords

Sacrocolpopexy; native tissue vaginal repair; apical repair; prolapse

Introduction

Surgeons who practice evidence-based reconstructive pelvic surgery seek the highest level of evidence for their surgical recommendations. Unfortunately, a significant knowledge gap exists for pelvic reconstructive surgeons who counsel the many women planning surgery for prolapse repair. Ideally, well-trained surgeons should be able to counsel and offer patients a variety of approaches and discuss the balance of benefits and risks of techniques based on high quality evidence including counseling regarding the impact of repair on bowel, bladder and sexual function. Although previous randomized trials have compared outcomes of open sacrocolpopexy (ASC) vs vaginal prolapse repair (VAR), these trials have drawbacks including small sample sizes, different types of procedures for both the abdominal and vaginal approaches and lack of standardized outcome measures, particularly for bowel, bladder and sexual function. [1–4] While data from these trials do show more durability in the short term for ASC, it is unclear whether or not functional outcomes are similar between the two approaches.

We aimed to compare success and adverse events between ASC and VAR utilizing data from three multi-center randomized trials that used standardized outcomes of pelvic reconstructive surgery for stage 2–4 pelvic organ prolapse. In our study, the pre-existing data from NICHHD trials included validated measurement of both anatomic, symptom and quality of life data as well as detailed descriptions of adverse events. We hypothesized that ASC would result in better anatomic and quality of life outcomes than VAR. Our ultimate goal is to inform the design, conduct and analysis of future randomized trials and to improve evidence regarding the surgical approach for women with stage 2–4 pelvic organ prolapse.

Materials and Methods

We present a retrospective study of participants enrolled in one of three NICHHD Pelvic Floor Disorders Network trials conducted in a total of 17 centers throughout the United States; all women underwent surgical correction of stage 2–4 pelvic organ prolapse with an apical suspension technique. The trials included in this study are the Colpopexy and Urinary Reduction Efforts (CARE) [5], Outcomes following Vaginal Prolapse Repair and Midurethral Sling (OPUS) [6], and the Operations and Pelvic Muscle Training in the Management of Apical Support Loss (OPTIMAL) trials [7]. The study designs and results of these trials have been previously published. Briefly, in the CARE trial, stress continent women underwent an abdominal sacrocolpopexy surgery for POP and were randomized to prophylactic Burch cystourethropepy continence surgery versus no Burch to evaluate the effectiveness of concomitant prophylactic continence surgery at the time of open abdominal surgery for POP.[5] Participants in the OPUS trial underwent vaginal prolapse surgery with a retropubic midurethral sling compared to a sham procedure to evaluate the efficacy of concomitant prophylactic continence surgery at the time of vaginal surgery for POP.[7] In both CARE and OPUS, women were not randomized to different types of prolapse repair. However, the OPTIMAL trial was designed with the primary aim to compare two native tissue vaginal approaches for the repair of apical POP and women were randomized to sacrospinous or uterosacral colpopexy.[6] The CARE and OPTIMAL trials were designed to

follow patients 2 years after surgery while the OPUS trial was designed to follow patients to one year after surgery.

For this study, we defined two separate groups; an abdominal approach repair group (ASC) and a vaginal approach repair group (VAR). We excluded women who underwent colpocleisis or vaginal mesh procedures for prolapse and women whose only apical procedure was ligation of the peritoneal sac or trachelectomy. For the abdominal ASC group we included women in the CARE trial. For the VAR group, we included women in the OPUS and OPTIMAL trials who underwent either ilioococcygeal, McCall's culdoplasty, sacrospinous or uterosacral colpopexy. We combined anterior colporrhaphy with abdominal paravaginal repairs to an "anterior repair" variable; all colporrhaphies were performed vaginally, and all paravaginal repairs were performed abdominally. We also combined posterior repair and perineorrhaphy into a "posterior repair" variable, as surgeons vary widely in their definition of how they perform these two repairs and there is likely crossover between the two techniques.[8]

Our primary outcome was success after POP surgery which was defined as the absence of bothersome bulge symptoms, no prolapse beyond the hymen, and no subsequent retreatment of prolapse up to 24 months. Bothersome bulge was measured by the Pelvic Organ Prolapse Distress Inventory (POPDI)(9) Question 5 (i.e. response of "No" to "Do you usually have a bulge or something falling out that you can see or feel in the vaginal area?" or "Not at all" to "If yes, how much does it bother you"). No prolapse beyond the hymen was measured on POPQ examination (i.e. measure of less than or equal to 0 on points Ba, C, and Bp).[10,11] Participants failing any one of three criteria above were considered to be surgical failures; women whose status could not be determined due to missing data for the three criteria were excluded from this analysis. Our secondary outcomes were symptom and quality of life measures. POPQ examinations, the Pelvic Floor Distress Inventory-20 (PFDI-20), the Pelvic Floor Impact Questionnaires-7 (PFIQ-7), and Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire-12 (PISQ-12) measures were administered at baseline and each follow-up visit.[9,12,13] The PFDI-20 comprised the Urinary Distress inventory (UDI), Colorectal Anal Distress Inventory (CRADI) and POPDI subscales. The PFIQ-7 comprised the Urinary Impact Questionnaire (UIQ), the Colorectal Anal Impact Questionnaire (CRAIQ) and the Pelvic Organ Prolapse Impact Questionnaire (POPIQ) subscales. Higher scores on the PFDI-20 and PFIQ-7 indicate greater bother and negative impact on quality of life, respectively, and higher PISQ-12 scores indicate better sexual function.

Complications and serious adverse events (SAE) were recorded on standardized forms for all trials. Perioperative complications were recorded up to 6 weeks postoperatively and included blood transfusions, deep vein thrombosis, pulmonary embolus and injuries to the ureters, bladder, urethra, bowel, vascular system and nerves. Only serious adverse events were recorded consistently across all studies after the perioperative period, from six weeks to 1–2 years postoperatively. These events were categorized using the Dindo complication scale.[14]

Demographics and baseline characteristics were compared between treatment groups using analysis of variance techniques for continuous normally distributed measures, Kruskal-

Wallis tests for non-normally distributed scale measures, mean score tests using standardized rank scores for ordinal categorical measures, and chi-square tests for general association for categorical measures. By design, the timing of follow-up visits varied by study. Success and QOL outcomes measured at multiple visits were analyzed using longitudinal mixed effects models (for continuous measures) or generalized linear models with empirical variance estimates (for binary measures) to obtain valid outcome estimates at specific visit times, accounting for data missing at random or missing completely at random due to the varied planned visits. Comparisons between groups controlled for center where possible as well as age, BMI, initial POPQ stage, prior prolapse repair and concurrent anterior or posterior repair except for events that occurred rarely. Additionally, models for PFDI-20, PFIQ-7 and PISQ-12 scores also controlled for the corresponding baseline score. Hypotheses for these outcomes were tested using contrast statements for assessing whether differences existed for the two groups across study follow-up as well as at individual visit times. Serious adverse events were graded by the Dindo score and compared between groups using analysis of covariance techniques for continuous measures, covariate adjusted logistic models for categorical measures, and covariate adjusted mean score tests using modified ridit scores for ordinal categorical measures. Due to low rates of occurrence, the percent of subjects experiencing specific complications during the perioperative and six week postoperative period was compared between treatment groups using a Fisher's exact test without adjustments.

Results

For these analyses 1022 women met inclusion criteria out of 1159 eligible from the parent studies. Figure 1 outlines the contribution to the study population from each of the parent studies. On average, participants in the ASC group were older, had lower BMI, and were more likely to be White, post-menopausal, and privately insured. Of the 701 patients who had vaginal surgery, 296 (42%) had outpatient surgery, 402 (57%) had inpatient surgery, and 3 (1%) had missing information. Of the 402 inpatients, the mean (SD) length of stay was 1.4 (0.7) days with a median length of stay of 1 day. All 321 patients who had ASC surgery were inpatients; they had a mean (SD) length of stay of 2.8 (1.1) days with a median length of stay of 3 days. In addition, they were more likely to have undergone prior incontinence or prolapse procedures. (Table 1) Importantly, they did not differ in rates of sexual activity, mean number of vaginal births, smoking history or SF-36 physical component scores. Women in the ASC group had more severe prolapse as measured by the POPQ, and reported less bother preoperatively from urinary and colorectal symptoms on the PFDI-20, and less quality of life impact on the PFIQ-7. Interestingly, despite differences in severity of prolapse as measured by the POPQ, baseline POPDI subscale scores were not different between groups. (Table 2) As is common with pelvic reconstructive surgery, women underwent a variety of concomitant procedures. (Table 3)

For our composite definition of success, outcomes were better in the ASC group at every time point. Overall treatment success was higher in the sacrocolpopexy group (OR:6.00, 95% CI:3.45–10.44). (Table 4) Likewise POPQ measurement of points Ba and C were better in the ASC group at all time points. Outcomes in the posterior compartment were similar

between groups at all time points. Retreatment of prolapse was low in both groups with only 2% of the ASC and 5% of the VAR group reporting retreatment prior to 24 months.

Bowel and bladder function as measured by the PFDI-20 and PFIQ-7 improved in both groups. (Table 5) Overall, adjusted results showed no difference in improvement between groups for PFDI-20 or PFIQ-7, including no difference in the UDI, POPDI, CRADI, UIQ, POPIQ and CRAIQ subscale scores. Improvement of POPDI scores were slightly greater at 24 months in the ASC group, but no difference was seen before this time point. PISQ-12 scores showed no difference in improvement between groups.

Table 6 displays the adverse events. Although serious adverse events were more common in the open sacrocolpopexy group at 6 weeks and one year, after statistically adjusting for center, apical procedure type and occurrence of posterior or anterior procedure, the groups were similar. Visceral injury, transfusion, pulmonary embolus and deep vein thrombosis were rare. Mesh erosion rates have previously been reported in the parent studies; for the OPUS trial, there were no mesh erosions, for the OPTIMAL study there were two erosions and in the CARE trial there were twelve.^{5,6,7} Neither serious adverse events rates nor Dindo ratings were different over the follow-up period. (Table 6)

Discussion

Two years following surgery, open ASC is associated with better composite outcome success rates and no significant differences in adverse events than vaginal repair of prolapse. Patient quality of life and symptom bother outcomes were similar and low reoperation rates were observed for both groups. Published symptom and anatomic outcomes, complications and reoperation rates for these procedures have significant limitations. A meta-analysis of comparative studies reported improved anatomic outcomes with colpopexy over native tissue repair with an increased risk of adverse events; however there was insufficient evidence to make any statements regarding the impact on bowel or bladder function.[15] Three published randomized trials that have compared open ASC to SSLF are summarized in a second meta-analysis.[1–4] That study supported superior anatomic outcomes for open ASC, but with longer operating times and longer recovery. Because of the transition to minimally invasive routes for ASC, the authors of the meta-analysis concluded that further evidence comparing minimally invasive approaches to ASC and vaginal repairs with and without mesh are needed.[1] Thus, existing randomized data directly comparing ASC and VAR prolapse repairs do not allow an evidence-based decision regarding the best route of apical prolapse surgery for each patient with prolapse.[1] In our retrospective study, combining data from three NICHD trials allowed us to evaluate a large number of women with validated anatomical, quality of life, bowel and bladder and sexual function outcomes as well as co evaluate adverse events throughout postoperative follow-up, permitting a comparison of the risks and benefits that often inform surgical decision making.

Serious adverse events did not differ between groups. Individual events commonly associated with surgery including thrombosis, pulmonary embolus and ureteral injury were very low and we likely did not have enough power to detect differences between groups. Although perioperative complications after sacrospinous ligament fixation are uncommon,

the consequences for individual affected patients can be significant. Buttock pain occurs in 3% but is usually self-limited, whereas sacral/pudendal neurovascular injury can result in transfusion in 2% and life-threatening hemorrhage in 0.2%.[16] In this study, transfusion was rare and occurred in both cohorts. Ureteral kinking or injury is commonly associated with transvaginal uterosacral colpopexy; however, most of these are identified intraoperatively and only 0.6% of patients require interval ureteral reimplantation.[17] Immediate perioperative complications of open ASC include wound complications in 4.6%, hemorrhage/transfusion in 4.4%, and visceral injury in 1–3.1%. We did find more ureteral kinking in our vaginal repair group but long-term sequelae from these injuries was low. Other visceral injuries were very low in both groups. Erosion of colpopexy material is one of the main concerns with ASC, occurring in 3.4% of 2,178 cases 3 years after surgery regardless of the type of material used, and requiring reoperation in 3% of women having ASC.[18] In the CARE trial from which our ASC cases were gathered, mesh erosion was thought to occur only in the first few years after surgery. However, longer follow-up in this cohort has documented a 10.5% rate of mesh erosion by seven years post operatively.[19] The CARE trial did allow multiple forms of synthetic mesh, some of which are no longer commonly used. In addition, the anatomical failure rate in the long term CARE followup was much higher than anticipated and ranged from 24 to 48%, depending on the definition used.

Our retrospective comparison benefited from the combined data from three large multicenter randomized trials with well characterized subjects using the same validated pelvic floor symptom distress and impact measures and systematic collection of adverse events. It allowed a robust comparison of prospectively collected one- and two-year outcomes in women undergoing a vaginal apical reconstructive surgery to those women undergoing an open abdominal approach. These data should be considered in light of their limitations. A comparative retrospective study has inherent biases regarding patient allocation. Patient characteristics were significantly different in the groups, with the ASC group being older, having greater prolapse, more previous surgeries for prolapse repair, and less bothersome urinary and bowel symptoms at baseline. Although we detected better outcomes in the ASC group, the baseline differences between groups may have diminished the differences observed. Despite excellent patient follow-up and standardized data collection, one of the two vaginal trials only collected 12-month outcomes, and the outcomes for times beyond 12 months were inferred using longitudinal mixed effects models (for continuous measures) or generalized linear models with empirical variance estimates (for binary measures) to obtain valid outcome estimates at specific visit times, accounting for data missing at random or missing completely at random due to the varied planned visits. These assumptions may not be correct and may have favored the VAR group underestimating the observed better outcomes in the ASC group.

Surgical techniques have evolved with time. The three studies in this analysis did not include transvaginal mesh or minimally invasive colpopexy procedures, and we do not have data on why patients were offered a vaginal or abdominal approach to their repair. Therefore, we are limited in our ability to comment on the role of these procedures in pelvic organ prolapse repair. A higher number of patients had undergone prior prolapse repairs, and a history of prior repair may have important implications on success of the current attempt at repair.

Surgical technique varies with individual surgeons and technique may account for some of the differences seen. It is possible that there may have been other differences that we did not measure or control for that influenced our findings.

In conclusion, in a careful examination of pre-existing datasets from three large trials of prolapse repair, open sacrocolpopexy was more likely to result in prolapse treatment success and was not observed to be significantly associated with greater rates of serious adverse events following surgery compared to vaginal repair. Bowel, bladder and prolapse functional results improved in both groups similarly. A randomized trial of vaginal and minimally invasive abdominal surgical approaches in women with apical prolapse with longer-term outcome time-points accompanied by cost effectiveness and robust adverse event analyses would more fully inform surgical practice and counseling.

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Brief Summary

In a retrospective analysis, open sacrocolpopexy when compared to vaginal apical repairs results in greater composite treatment success without increases in adverse events.

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Figure 1.
Strobe outline of participants.

Table 1

Patient Characteristics

Characteristic	Abdominal (N=321)	Vaginal (N=701)	P-value [1]
Age at surgery, mean years (SD)	61.5 (10.2)	59.5 (10.4)	0.005
BMI* (kg/m ²), mean (SD)	27.0 (4.5)	28.4 (5.4)	<0.001
Primary race, n (%)			<0.001
Black/African American	17 (5%)	41 (6%)	
White	298 (93%)	604 (86%)	
Other	6 (2%)	54 (8%)	
Unknown			
Hispanic/Latina Ethnicity, n (%)	9 (3%)	127 (18%)	<0.001
Insurance, n (%)			<0.001
Medicaid/Medicare	29 (9%)	194 (28%)	
Private/HMO	279 (87%)	496 (71%)	
Self-Pay	8 (2%)	10 (1%)	
Other	5 (2%)	1 (0%)	
Vaginal deliveries, mean (SD)	3.0 (1.4)	3.0 (1.9)	0.274
History of caesarean delivery, n (%)	16 (5%)	59 (8%)	0.050
Prior urinary incontinence surgery, n (%)	22 (7%)	23 (3%)	0.010
Prior prolapse surgery, n (%)	125 (39%)	58 (8%)	<0.001
Post-Menopausal, n (%)	279 (87%)	528 (75%)	<0.001
Currently using estrogen replacement therapy, n (%)	129 (40%)	231 (33%)	0.025
Current smoker, n (%)	23 (7%)	51 (7%)	0.950
Diabetes Mellitus, n (%)	16 (5%)	84 (12%)	<0.001
Cardiac impairment, n (%)	48 (15%)	110 (16%)	0.823
SF36 Physical component score, mean (SD)	45.4 (9.6)	45.3 (9.9)	0.869
Sexually active, n (%)	161 (50%)	326 (47%)	0.672

[1] P-values based on comparing characteristics between groups while excluding responses of unknown

* Body Mass Index

Table 2

Baseline prolapse measurements, Pelvic Floor Distress Inventory-20, Pelvic Floor Impact Questionnaire-7 and Pelvic Organ Prolapse Incontinence Sexual Questionnaire-12

Characteristic	Abdominal (N=321)	Vaginal (N=701)	P-value [1]
POPQ [*] stage, n (%)			<0.001
2	44 (14%)	227 (32%)	
3	217 (68%)	434 (62%)	
4	60 (19%)	39 (6%)	
Unknown	0 (0%)	1 (0%)	
Ba, mean (SD)	3.3 (2.7)	2.2 (2.3)	<0.001
C, mean (SD)	1.4 (4.6)	-0.6 (3.7)	<0.001
Bp, mean (SD)	1.1 (3.6)	-0.5 (2.4)	<0.001
UDI ^{**} , mean (SD)	61.0 (40.7)	92.1 (61.4)	<0.001
POPDI ^{***} , mean (SD)	107.5 (67.4)	109.1 (67.4)	0.730
CRADI ⁺ , mean (SD)	70.4 (69.4)	84.8 (78.1)	0.005
UIQ [#] , mean (SD)	47.0 (50.4)	101.8 (97.1)	<0.001
POPIQ ^{\$} , mean (SD)	43.7 (56.4)	81.4 (96.7)	<0.001
CRAIQ [^] , mean (SD)	29.3 (50.0)	53.2 (82.2)	<0.001
PISQ-12 ^{^^} , mean (SD)	33.7 (7.1)	32.5 (7.2)	0.091

[1] P-values based on comparing characteristics between groups while excluding responses of unknown

* Pelvic Organ Prolapse Quantification Scale;

** Urinary Distress Inventory;

*** Pelvic Organ Prolapse Distress Inventory;

⁺ Colorectal Anal Distress Inventory;

[#] Urinary Impact Questionnaire;

^{\$} Pelvic Organ Prolapse Impact Questionnaire;

[^] Colorectal Anal Impact Questionnaire;

^{^^} Pelvic Organ Prolapse Urinary Incontinence Sexual Questionnaire

Table 3

Surgical procedures

Surgery	Abdominal (N=321)	Vaginal (N=701)	P-value ^[1]
Anterior repair, n (%)			<0.001
Anterior Colporrhaphy with/without Paravaginal Repair from vaginal approach	0 (0%)	442 (63%)	
Abdominal Paravaginal Repair	59 (18%)	0 (0%)	
Posterior Colporrhaphy/Perineorrhaphy, n (%)	89 (28%)	341 (49%)	<0.001
Hysterectomy and/or Oophorectomy, n (%)	176 (55%)	494 (70%)	<0.001
Stress incontinence procedures, n (%)			<0.001
Burch	154 (48%)	0 (0%)	
Retropubic Midurethral Sling	0 (0%)	526 (75%)	
General Anesthesia, n (%)	318 (99%)	684 (98%)	0.062
Operating Room Time, mean (SD)	180.2 (57.9)	148.7 (49.0)	<0.001

^[1] P-values based on comparing characteristics between groups while excluding responses of unknown

Table 4**Prolapse Treatment Outcomes**

Outcomes at 3,12 and 24 month follow-up	Abdominal (N=321)	Vaginal (N=701)	Adjusted difference or odds ratio [1]	Raw P-value [2]	Adjusted P-value [2]
Change in Ba from baseline, mean cm (SD)					
Overall	-1.86	-1.01	-0.84	<0.001	<0.001
Month 3	-2.02	-1.46	-0.56	<0.001	<0.001
Month 12	-1.81	-0.84	-0.97	<0.001	<0.001
Month 24	-1.74	-0.74	-0.99	<0.001	<0.001
Change in C from baseline, mean cm (SD)					
Overall	-8.13	-5.63	-2.50	<0.001	<0.001
Month 3	-8.30	-5.88	-2.42	<0.001	<0.001
Month 12	-8.19	-5.48	-2.71	<0.001	<0.001
Month 24	-7.90	-5.53	-2.37	<0.001	<0.001
Change in Bp from baseline, mean cm (SD)					
Overall	-2.18	-2.09	-0.08	0.381	0.416
Month 3	-2.36	-2.21	-0.16	0.184	0.166
Month 12	-2.09	-2.09	-0.01	0.842	0.939
Month 24	-2.07	-1.99	-0.08	0.458	0.525
Absence of bothersome bulge, n (%)					
Overall			7.82 (2.75,22.23)	<0.001	<0.001
Month 3	301 (100%)	318 (98%)	11.37 (1.23,105.11)	0.022	0.019
Month 12	298 (98%)	576 (90%)	7.99 (2.75,23.26)	<0.001	<0.001
Month 24	279 (96%)	261 (87%)	5.25 (2.25,12.28)	<0.001	<0.001
Support above hymen, n (%)					
Overall			6.69 (3.74,11.98)	<0.001	<0.001
Month 3	301 (98%)	278 (88%)	9.62 (3.87,23.96)	<0.001	<0.001
Month 12	269 (95%)	503(81%)	6.03 (3.17,11.49)	<0.001	<0.001
Month 24	235 (94%)	258(85%)	5.17 (2.60,10.28)	<0.001	<0.001

Outcomes at 3,12 and 24 month follow-up	Abdominal (N=321)	Vaginal (N=701)	Adjusted difference or odds ratio [1]	Raw P-value [2]	Adjusted P-value [2]
No report of retreatment, n (%)					
Overall			#	#	#
Month 3	319 (99%)	331 (100%)	#	#	#
Month 12	316 (98%)	659 (98%)	#	#	#
Month 24	313 (98%)	331 (95%)	#	#	#
Success [*] , n (%)					
Overall			6.00 (3.45,10.44)	<0.001	<0.001
Month 3	282 (97%)	271 (87%)	6.36 (2.90,13.92)	<0.001	<0.001
Month 12	259 (93%)	446 (74%)	7.04 (3.79,13.11)	<0.001	<0.001
Month 24	216 (99%)	212 (73%)	4.83 (2.75,8.49)	<0.001	<0.001

[1] For continuous outcomes, adjusted means and differences are presented based on repeated measure mixed models adjusting for center where possible as well as apical surgical type, occurrence of anterior or posterior surgeries, prior POP surgery, age, BMI and POP-Q stage. For binary outcomes, proportions and adjusted odds ratios of vault vs. uterovaginal prolapse are presented based on subjects with available data at the visit.

[2] Raw p-values based on analyses with no adjustments. Adjusted p-values based on repeated measure mixed models adjusting for center where possible as well as apical surgical type, occurrence of anterior or posterior surgeries, prior POP surgery, age, BMI and POP-Q stage

* Success defined as absence of bothersome bulge symptoms as measured by the PFDI Question #5 (i.e. response of "No" to "Do you usually have a bulge or something falling out that you can see or feel in the vaginal area?" or "Not at all" to "If yes, how much does it bother you"), no prolapse beyond the hymen on POPQ examination (i.e. measure of less than or equal to 0 on Ba, C, and Bp) and no subsequent treatment for prolapse.

Not estimated

Table 5

Pelvic Floor Distress Inventory -20 (PFDI-20), Pelvic Floor Impact Questionnaire-7 (PFIQ-7) Subscale Scores and Pelvic Organ Prolapse Urinary Incontinence Sexual Questionnaire 12 (PISQ-12) Results

Outcome	Time of follow-up	Abdominal, Change from Baseline (N=321)	Vaginal, Change from Baseline (N=701)	Adjusted difference [1]	Raw P-value [2]	Adjusted P-value [2]
UDI ^{**} , mean (SD)	Overall	-51.16	-55.16	4.00 (-3.09,11.10)	<0.001	0.269
	Month 3	-48.96	-58.34	9.38 (1.73,17.03)	<0.001	0.016
	Month 12	-53.30	-58.81	5.52 (-1.92,12.95)	<0.001	0.146
	Month 24	-51.21	-48.32	-2.88 (-10.76,4.99)	<0.001	0.473
POPDI ^{***} , mean (SD)	Overall	-77.50	-77.10	-0.40 (-8.62,7.83)	0.243	0.925
	Month 3	-77.30	-83.65	6.35 (-2.74,15.45)	0.966	0.171
	Month 12	-78.09	-80.40	2.31 (-6.42,11.04)	0.641	0.604
	Month 24	-77.11	-67.26	-9.85 (-19.11,-0.60)	0.009	0.037
CRADI [†] , mean (SD)	Overall	-42.01	-43.40	1.39 (-7.29,10.07)	0.081	0.753
	Month 3	-42.75	-47.41	4.66 (-5.01,14.33)	0.142	0.345
	Month 12	-41.79	-48.46	6.67 (-2.59,15.93)	0.004	0.158
	Month 24	-41.49	-34.34	-7.15 (-17.01,2.70)	0.672	0.155
UIQ [#] , mean (SD)	Overall	-45.42	-51.81	6.39 (-4.69,17.46)	<0.001	0.258
	Month 3	-39.35	-53.91	14.55 (2.62,26.49)	<0.001	0.017
	Month 12	-49.19	-58.32	9.13 (-2.45,20.71)	<0.001	0.122
	Month 24	-47.72	-43.20	-4.53 (-16.72,7.66)	<0.001	0.466
POPPIQ [§] , mean (SD)	Overall	-44.40	-51.67	7.26 (-1.81,16.33)	<0.001	0.116
	Month 3	-42.70	-56.31	13.61 (3.73,23.49)	<0.001	0.007
	Month 12	-44.95	-57.64	12.70 (3.17,22.23)	<0.001	0.009
	Month 24	-45.57	-41.05	-4.52 (-14.55,5.51)	<0.001	0.377
CRAIQ [^] , mean (SD)	Overall	-21.27	-25.95	4.68 (-4.42,13.78)	<0.001	0.313
	Month 3	-19.66	-30.69	11.04 (0.90,21.17)	<0.001	0.033
	Month 12	-23.85	-33.49	9.63 (-0.07,19.34)	<0.001	0.052

Outcome	Time of follow-up	Abdominal, Change from Baseline (N=321)	Vaginal, Change from Baseline (N=701)	Adjusted difference [1]	Raw P-value [2]	Adjusted P-value [2]
	Month 24	-20.31	-13.67	-6.64 (-16.95,3.68)	0.029	0.207
PISQ-12 ^{^,^} , mean (SD)	Overall	3.41	4.47	-1.06 (-2.49,0.36)	0.088	0.142
	Month 3	3.51	4.37	-0.87 (-2.49,0.75)	0.426	0.294
	Month 12	3.44	5.02	-1.58 (-3.10,-0.07)	0.022	0.041
	Month 24	3.28	4.02	-0.74 (-2.38,0.89)	0.179	0.372

^{**} Urinary Distress Inventory

^{***} Pelvic Organ Prolapse Distress Inventory

⁺ Colorectal Anal Distress Inventory

[#] Urinary Impact Questionnaire

^{\$} Pelvic Organ Prolapse Impact Questionnaire

[^] Colorectal Anal Impact Questionnaire

^{^^} Pelvic Organ Prolapse Urinary Incontinence Sexual Questionnaire

Table 6**Complications and Adverse Events**

Adverse Event	Abdominal, (N=321)	Vaginal, (N=701)	P-value [1]	Adjusted P-value [2]
Serious Adverse Events, n (%)				
During First 6 Weeks Post-op	42 (13%)	38 (5%)	<0.001	0.104
During First Year Follow-up	83 (26%)	93 (13%)	<0.001	0.098
Serious Adverse Events per subject, mean (SD) (range)				
During First 6 Weeks Post-op	0.1 (0.4) (0–2)	0.1 (0.2) (0–2)	<0.001	0.276
During First Year Follow-up	0.3 (0.6) (0–3)	0.2 (0.4) (0–3)	<0.001	0.431
Maximum reported Dindo score during first 6 weeks post-op, n (%)			0.109	0.596
1	11 (3%)	3 (0%)		
2	17 (5%)	18 (3%)		
3	14 (4%)	16 (2%)		
4	0 (0%)	0 (0%)		
5	0 (0%)	0 (0%)		
Maximum reported Dindo score during first year follow-up, n (%)			0.890	0.983
1	11 (3%)	6 (1%)		
2	19 (6%)	27 (4%)		
3	50 (16%)	58 (8%)		
4	3 (1%)	1 (0%)		
5	0 (0%)	0 (0%)		
Specific Adverse Events Intraoperative and Through 6 weeks Postoperatively				
Ureteral injury during surgery, n (%)	1 (0%)	16 (2%)	0.018	n/a
Blood transfusion during hospitalization, n (%)	12 (4%)	13 (2%)	0.081	n/a
Cystotomy/urethral injury, n (%)	4 (1%)	54 (8%)	<0.001	n/a
Bowel injury, n (%)	0 (0%)	1 (0%)	1.000	n/a
Vascular injury, n (%)	1 (0%)	0 (0%)	0.314	n/a
Nerve injury, n (%)	0 (0%)	2 (0%)	1.000	n/a
Deep vein thrombosis, n (%)	1 (0%)	1 (0%)	0.531	n/a

Adverse Event	Abdominal, (N=321)	Vaginal, (N=701)	P-value [1]	Adjusted P-value [2]
Pulmonary embolism, n (%)	2 (1%)	1 (0%)	0.235	n/a

[1] P-values based on comparing outcomes between groups while excluding missing outcomes. For variables with small cell counts, p-values are based on unadjusted, Fisher exact tests.

[2] Adjusted p-value controls for center, apical procedure type and occurrence of posterior or anterior procedure.