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Risk Factors for Surgical Failure and Worsening Pelvic Floor Symptoms Within 5 Years After Vaginal Prolapse Repair

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Abstract

OBJECTIVE: To assess independent risk factors for surgical failure and worsening pelvic floor symptoms within 5 years after vaginal prolapse surgery.

METHODS: This secondary analysis includes OPTIMAL (Operations and Pelvic Muscle Training in the Management of Apical Support Loss) (n=374) and E-OPTIMAL (Extended) (n=285) trial participants. Surgical failure was defined as apical descent greater than one third of the total vaginal length, anterior or posterior vaginal wall past the hymen, subsequent surgery or bothersome vaginal bulge. Worsening pelvic floor symptoms were defined as increases from baseline as large as the minimally important difference for subscale scores of the Pelvic Floor Distress Inventory: 11 for the Urinary Distress Inventory and Colorectal-Anal Distress Inventory and 34.3 for the Pelvic Organ Prolapse Distress Inventory. Outcomes were measured at 6 months then 1, 2, 3, 4, and 5 years. Chi-square and t test results from bivariate models and clinical relevance were used to inform final models.

RESULTS: Baseline risk factors for surgical failure were Hispanic ethnicity (adjusted odds ratio [aOR] 1.92, 95% CI 1.17–3.15), perineal body (aOR 1.34, 95% CI 1.09–1.63), and pretreatment Pelvic Organ Prolapse Distress Inventory score (aOR 1.16, 95% CI 1.05–1.28). Risk factors for worsening of pelvic floor symptoms were pretreatment Pelvic Organ Prolapse Distress Inventory

*A list of members of the PFDN are in Appendix 1 online at http://links.lww.com/AOG/C46.

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score (aOR 0.75, 95% CI 0.60–0.94) for worsening Pelvic Organ Prolapse Distress Inventory score, vaginal deliveries (aOR 1.26, 95% CI 1.10–1.44) and pretreatment Urinary Distress Inventory score (aOR 0.86, 95% CI 0.80–0.93) for worsening Urinary Distress Inventory score, and age (aOR 1.03, 95% CI 1.01–1.05) and pretreatment Colorectal-Anal Distress Inventory score (aOR 0.95, 95% CI 0.92–0.98) for worsening Colorectal-Anal Distress Inventory score.

CONCLUSIONS: Hispanic ethnicity, larger preoperative perineal body, and higher pretreatment Pelvic Organ Prolapse Distress Inventory scores were risk factors for surgical failure up to 5 years after vaginal prolapse repair. Participants with higher baseline Pelvic Floor Distress Inventory scores were less likely to worsen. Risk factors for worsening Urinary Distress Inventory and Colorectal-Anal Distress Inventory scores included more vaginal deliveries and increased age, respectively.

CLINICAL TRIAL REGISTRATION: NCT00597935, NCT01166373.

Surgery for pelvic organ prolapse is generally performed transvaginally using native tissues. The predominant apical repair approaches are sacrospinous ligament fixation or uterosacral ligament suspension.[1–4] Comparative data for long-term outcomes after these procedures had been limited until the recently published OPTIMAL (Operations and Pelvic Muscle Training in the Management of Apical Support Loss) trial.

The OPTIMAL trial was conducted at nine medical centers that compared 2-year outcomes in women randomized to sacrospinous ligament fixation or uterosacral ligament suspension, and either perioperative behavioral therapy with pelvic floor muscle training or usual care.[5] Improvements were seen in quality of life, sexual function, and body image without differences between groups in anatomic and functional outcomes; however surgical success rates were suboptimal. Among participants who enrolled in the E-OPTIMAL (Extended) study, there were no group differences in surgical failure, anatomic success or symptom scores up to 5 years after surgery.[6]

Given the undesirable rate of surgical failure, additional research is needed to understand the risk factors associated with recurrence and re-operation for pelvic organ prolapse. Predictive modeling has provided accurate short term (1 year) recurrence and reoperation estimates and identified risk factors for further investigation.[7] A systematic review of pelvic organ prolapse found several risk factors for primary prolapse but the only consistent risk factor for recurrence was “preoperative stage” in two of the 10 studies included in the review.[8] In this planned secondary analysis, we provide multivariable modeling of independent risk factors for surgical failure and new or worsening pelvic floor symptoms up to 5 years after transvaginal native tissue pelvic organ prolapse repair.

METHODS

Enrollment for the OPTIMAL trial occurred from January 2008 to March 2011 with standardized surgery for pelvic organ prolapse consisting of a unilateral sacrospinous ligament fixation procedure[9,10] or a bilateral uterosacral ligament suspension procedure.[11] Participants had stage 2–4 apical prolapse (determined by baseline pelvic organ prolapse quantification [POP-Q] examination) with symptomatic stress urinary incontinence and

underwent a vaginal suspension surgery with a planned hysterectomy (in participants with a uterus) and retropubic mid-urethral sling. Additional procedures were performed at the surgeon's discretion.[5,12] Participant masking to the surgical intervention continued until all trial participants completed follow-up for the E-OPTIMAL trial.

Participants randomized to perioperative behavioral therapy with pelvic floor muscle training visited centrally trained pelvic floor therapists 2–4 weeks before and 2, 4–6, 8, and 12 weeks after surgery. Each participant practiced pelvic floor muscle exercises and received individualized education on behavioral strategies to reduce urinary and colorectal symptoms during each visit.[5,12]

Outcome measures were assessed at 6, 12, and 24 months. Participants who completed their 24 month participation in the OPTIMAL trial were approached for enrollment in the E-OPTIMAL trial.[6] Institutional review board approval was obtained at each site. Women who lived in skilled nursing facilities were excluded. Eligible participants for the E-OPTIMAL trial were enrolled between April 2010 and February 2013, then followed up to 5 years after their index surgery from April 2011 through June 2016. Participants unable to return for annual visits were included if they participated in the telephone interview portion of the study. In-person evaluations were performed at the clinical site, and telephone interviews were conducted by the central facility at the Data Coordinating Center annually during postoperative years three through five. Evaluators of outcome assessments remained masked to surgical and behavioral therapy with pelvic floor muscle training randomizations. All participants in the OPTIMAL trial who underwent behavioral therapy and surgical randomizations were included in this analysis.

The primary outcome for the E-OPTIMAL trial was the time-to-event outcome of surgical failure up to 5 years after surgery. Measurement of prolapse was based on the POP-Q system.[13] Surgical failure was present if any of the following criteria were met: 1) POP-Q point C descended with Valsalva more than one third of total vaginal length; 2) POP-Q points Aa, Ba, Ap, or Bp with Valsalva were beyond the hymen;3) any bothersome bulge symptoms were reported by the participant (ie, any response other than "not at all" to the question "How much does this bother you?"), with an affirmative response to the question, "Do you usually have a sensation of bulging or protrusion from the vaginal area?" or, "Do you usually have a bulge or something falling out that you can see or feel in the vaginal area?" on the Pelvic Floor Distress Inventory[14]; or 4) the participant underwent surgery or elected to use a pessary for prolapse at any point during follow-up. In this secondary analysis, surgical failure is reported at 6 months then at 1, 2, 3, 4, and 5 years after surgery using the OPTIMAL trial definition of surgical failure.

Secondary outcomes included quality of life measures. Subscales of the Pelvic Floor Distress Inventory (higher scores indicate worse symptoms)[14] were collected pretreatment, on enrollment in the OPTIMAL trial, and during each of the follow-up assessments. Subscales of the Pelvic Floor Distress Inventory include the Pelvic Organ Prolapse Distress Inventory (range 0–300),[15] the Urinary Distress Inventory (range 0–300[16]), and the Colorectal-Anal Distress Inventory (range 0–400[17]). Clinically significant changes in pelvic floor symptoms from baseline are reported for each of the subscales of the Pelvic Floor

Distress Inventory by year of follow-up. The minimal clinically important difference was 11 for the Urinary Distress Inventory, 11 for the Colorectal-Anal Distress Inventory, and 34.3 for the Pelvic Organ Prolapse Distress Inventory.[18] Worsening of Urinary Distress Inventory, Colorectal-Anal Distress Inventory, and Pelvic Organ Prolapse Distress Inventory scores was defined as an increase in score between baseline and follow-up that was at least as large as the minimally important difference.

Risk factors for surgical failure include participant demographics (age, ethnicity, racial background), estrogen use, medical comorbidities, previous prolapse and incontinence surgery, pretreatment POP-Q measurements, pelvic muscle assessment, concurrent prolapse surgery, sexual activity, pretreatment Pelvic Organ Prolapse Distress Inventory subscale scores and baseline physical activity determined from question 3 of the Short-Form 36 Health Status questionnaire ("Does your health now limit you in these activities? If so, how much? Running, lifting heavy objects, or participating in strenuous sports?").

Chi-square tests and *t* tests were used to compare pretreatment Pelvic Floor Distress Inventory subscale scores between surgical failures compared with successes and participants who did compared with did not report worsening of symptoms at each time point. Binary outcomes from 6 months through 5 years were modeled using generalized linear mixed models with a logit link and fixed and random effects for time. Variables that were consistently associated with the outcome over time at a statistical significance level of $P<.2$ and that were considered to be clinically relevant were included in the final model (see unadjusted models in Appendices 2 and 3, available online at http://links.lww.com/AOG/C46). Baseline variables with low numbers (such as menstrual status and sexual activity) were excluded from the model or collapsed into fewer categories (such as race–ethnicity). Baseline variables with inconsistent effects over time were also excluded from the models (see outcomes by timepoint in Appendix 4, available online at http://links.lww.com/AOG/C46).

Each Pelvic Floor Distress Inventory subscale was modeled longitudinally using general linear mixed models with fixed and random effects for time. Models were constructed to predict change from baseline to 6 months through 5 years, calculated as postoperative subscale score minus pretreatment subscale score. If the postoperative subscale score was lower, indicating improvement, a negative Beta coefficient indicated that the risk factor was associated with improvement. If the risk factor was continuous or ordinal, each unit increase in the baseline value of the risk factor was associated with the corresponding amount of change in subscale value from baseline. Independent variables for these models were selected based on statistical significance at the $P<.2$ level in unadjusted modeling and clinical importance. All analyses were conducted using SAS 9.4.

RESULTS

Of the 374 randomized participants from the OPTIMAL trial, the E-OPTIMAL trial enrolled 285; pretreatment characteristics of participants in the E-OPTIMAL trial were similar to those for participants in the OPTIMAL trial (Table 1). The participants in the OPTIMAL trial who were classified as having surgical failure by anatomic or retreatment criteria at 24

months were less likely to enroll in the E-OPTI-MAL trial. The anatomic failure rate at 24 months was 20.3% (56/276) in participants in the E-OPTIMAL trial and 56.1% (23/41) in nonenrolled participants.[6]

In multivariable modeling, Hispanic ethnicity was associated with increased odds of surgical failure (adjusted odds ratio [aOR] 1.92, 95% CI 1.17–3.15, Table 2) and an average worsening in Pelvic Organ Prolapse Distress Inventory score of 11.6 points (95% CI 4.8–18.4) (Table 3). Perineal body length was associated with increased odds of surgical failure (aOR 1.34, 95% CI 1.09–1.63, Table 2); for each centimeter increase in baseline perineal body length, the Pelvic Organ Prolapse Distress Inventory score increased by 4.4 points (95% CI 1.8–6.9) and the Urinary Distress Inventory score increased by 6.3 points (95% CI 2.1–10.5) (Table 3). Each additional vaginal delivery was associated with an increased odds of an 11-point (minimal clinically important difference) worsening in the Urinary Distress Inventory score (aOR 1.26, 95% CI 1.10–1.44), and each year of age was associated with an increased odds of an 11-point (minimally important difference) worsening in the Colorectal-Anal Distress Inventory score (aOR 1.03, 95% CI 1.01–1.05) (Table 2). Additional risk factors identified for worsening pelvic floor symptoms included severe physical limitations at baseline (Short-Form 36 Health Status questionnaire Physical Limitation: “a lot”), which was associated with an increase of 10.3 points in the Pelvic Organ Prolapse Distress Inventory score (95% CI 2.9–17.7) (Table 3), and worsening of the Urinary Distress Inventory score in the small number of participants who categorized themselves as unsure of their menopausal status and were presumably perimenopausal at the start of the study (Table 3).

Whereas higher (more symptomatic) pretreatment Pelvic Organ Prolapse Distress Inventory scores were associated with increased odds of surgical failure (aOR 1.16, 95% CI 1.05–1.28) (Table 2), higher pretreatment Pelvic Organ Prolapse Distress Inventory scores (aOR 0.75, 95% CI 0.60–0.94), pretreatment Urinary Distress Inventory scores (aOR 0.86, 95% CI 0.80–0.93), and pretreatment Colorectal-Anal Distress Inventory scores (aOR 0.95, 95% CI 0.92–0.98) were associated with lower odds of meeting the criteria of minimally important clinical difference for worsening in Pelvic Organ Prolapse Distress Inventory, Urinary Distress Inventory, and Colorectal-Anal Distress Inventory scores, respectively (Table 2). For each unit increase in pretreatment Pelvic Organ Prolapse Distress Inventory score, there was an average improvement from baseline of 20.6 points (95% CI 20.66 to 20.59) (Table 3). Similarly, for each unit increase in the pretreatment Urinary Distress Inventory score, there was an average improvement from baseline of 20.74 points (95% CI 20.81 to 20.67); for each unit increase in pretreatment Colorectal-Anal Distress Inventory score, there was an average improvement from baseline of 20.61 points (95% CI 20.67 to 20.55) (Table 3).

DISCUSSION

This secondary analysis documented three risk factors for surgical failure up to 5 years after native tissue prolapse repair surgery, including one potentially modifiable factor (higher pretreatment Pelvic Organ Prolapse Distress Inventory score) and two no modifiable factors (Hispanic ethnicity, and larger preoperative perineal body measurement). Higher pretreatment Pelvic Organ Prolapse Distress Inventory, Urinary Distress Inventory, and

Colorectal-Anal Distress Inventory scores were associated with more improvement (reduction) in scores postoperatively and reduced likelihood of worsening (increasing score) by as much as the minimal clinically important difference. Each additional vaginal delivery increased the risk of worsening postoperative Urinary Distress Inventory score, and increased age was a risk factor for worsening Colorectal-Anal Distress Inventory score.

Although there are well-documented differences in racial and ethnic aspects to pelvic floor disorders,[19] the associations of Hispanic ethnicity with surgical failure and with worsening Pelvic Organ Prolapse Distress Inventory score have not previously been identified,[8,20] nor has there been a substantiated biological explanation. This risk factor may be related to factors present at the time of surgery or differing life experiences that affect surgical durability. Although this longitudinal study carefully characterized participants, we did not test any hypothesis regarding specific mechanistic factors (eg, heavy lifting) at baseline nor during follow-up. Although we did not examine the characteristics of Hispanic participants, age, body mass index (BMI, calculated as weight in kilograms divided by height in meters squared), and number of deliveries were all considered in the model building process; none of these factors were associated with surgical failure. Thus, it is unlikely that those characteristics account for the effect of Hispanic ethnicity. Hispanic ethnicity and higher baseline Pelvic Organ Prolapse Distress Inventory score were both associated with surgical failure in the final model, indicating that each was independently associated with the outcome even after controlling for the other.

The anatomic risk factor of the larger perineal body was surprising, as this is generally thought of as an anatomic indicator of less severe anatomic distortion. Because the perineal body length is measured during a Valsalva maneuver, it likely indicates perineal descent and disruption from the levator musculature. A longer perineal body may also correlate with a wider GH and thus a higher rate of anatomic failure after prolapse repair[21] though prior studies have not shown a consistent correlation between PB length and prolapse stage.[22] The decision to perform concomitant procedures such as a posterior repair or perineor-rhaphy were at the discretion of the operating surgeon. The length of the perineal body at baseline may have affected the decision to perform a concomitant procedure. A previously published secondary analysis of the OPTIMAL trial determined that the performance of a posterior repair at the time of apical suspension was not independently associated with surgical success. Preoperative genital hiatus was prognostic of prolapse recurrence regardless of concomitant posterior repair.[23]

Vaginal delivery and age are clearly associated with an increased risk of developing symptomatic pelvic floor disorders.[24,25] Thus, we were not surprised to see that prior vaginal delivery was identified as a risk factor for worsening urinary incontinence symptoms. Although this risk factor was not strongly associated with anatomic failure, it is well known that vaginal delivery is associated with a variety of persistent pathophysiologic changes in the pelvis.[26] The association of increased age with fecal incontinence has been well documented.[27]

The utility of performing analyses using the Pelvic Floor Distress Inventory scores as continuous outcome variables (change from baseline) and dichotomous (change by the

minimally important difference for failure) is to better characterize these secondary outcome measures. These models were largely consistent with respect to significant risk factors for worsening Pelvic Floor Distress Inventory subscale scores. The effect of severe physical limitations at baseline on the Pelvic Organ Prolapse Distress Inventory score is consistent with prior literature indicating that physical frailty may have an effect on outcomes of prolapse repair surgery.[28] The weak correlation of worsening Urinary Distress Inventory score in participants who may have been perimenopausal could also relate to the genitourinary syndrome of menopause.[29]

Pretreatment Pelvic Organ Prolapse Distress Inventory scores are potentially modifiable before surgery by treatment of the nonsurgical pelvic floor conditions. It is well known that patients scheduled to undergo pelvic organ prolapse–urinary incontinence surgery frequently have more than one pelvic floor disorder.[30] The pretreatment Pelvic Organ Prolapse Distress Inventory score reflects contributions from a variety of symptoms. In the presence of bothersome prolapse that warrants surgery, it is common to defer treatment of certain concomitant conditions such as urgency urinary incontinence, as there is some evidence that these symptoms are likely to change after surgery.[31] However, pretreatment Pelvic Organ Prolapse Distress Inventory score may serve as a proxy for the cumulative burden of multiple pelvic floor disorders that may not be completely addressed with surgery. This would explain our finding that the participants with the most bothersome symptoms at baseline reported meaningful postoperative improvement but were not as likely to meet the definition of surgical success.

One of the most interesting findings is that higher pretreatment Pelvic Organ Prolapse Distress Inventory scores were a risk factor for surgical failure, but higher pretreatment Pelvic Organ Prolapse Distress Inventory, Urinary Distress Inventory, and Colorectal-Anal Distress Inventory scores were also significantly associated with greater patient-perceived improvement from baseline scores. Although seemingly inconsistent, it may reflect the limitations of our definition of surgical success as a composite score of anatomic and subjective measures assessed at predetermined points in time. The analysis plan for this secondary outcome article was planned a priori when the OPTIMAL study was designed. This composite definition is consistent with the primary outcome measure for the OPTIMAL trial. Participants with the most symptoms pretreatment had the greatest opportunity for improvement and a higher probability of perceiving that their surgery was a success even if they did not meet the clinical definition of surgical success. These same participants with the highest pretreatment scores may also have had lower odds of worsening symptoms owing to a ceiling effect in which the pretreatment score was so high it was unlikely to increase further by the degree needed to meet the criteria of the minimally important difference. This finding is perhaps most useful for counseling patients contemplating undergoing surgery for prolapse who have fewer symptoms as there is less “opportunity” for them to improve; they may be more likely to be dissatisfied or report higher degree of bother from symptoms after surgery.

This study has many strengths, including the multicenter design with careful longitudinal assessment of participants over 5 years, use of validated measures to quantify anatomic and symptom status, hypothesis-driven analysis of prespecified aims and broad generalizability

across multiple races and ethnicities. Furthermore, a high percentage of participants contributed longitudinal follow-up data, and the cohort in the E-OPTIMAL trial was similar to the cohort in the OPTIMAL trial with respect to pretreatment characteristics. As with any study, there are limitations, including the choice of design, which allowed identification of associations without causal implications and a lack of mechanistic insights. Also, there is potential bias owing to loss of participants from the OPTIMAL trial, especially because the participants with surgical failures by 2 years were less likely to enroll in the E-OPTIMAL trial.[6] However, the statistical modeling methods used in this study assume that missing outcomes are "missing at random"; thus, the model results take into account that the unobserved outcomes at 3–5 years among participants who did not enroll in the E-OPTIMAL trial may be related to the data collected through 2 years. Finally, there are limitations with the use of any composite outcome measure, especially for surgical outcomes. For example, participants with higher presurgical Pelvic Organ Prolapse Distress Inventory scores had more potential for improvement in symptoms than women with lower presurgical scores or less bother. Despite meaningful improvement in symptoms, participants with higher presurgical symptom scores may still have been classified as having surgical failure based on anatomic criteria alone. Further research is needed to clarify the patient-preference and values for surgical outcomes of reconstructive prolapse procedures.

Clinicians are aware that better outcomes typically occur when treatment is initiated in milder forms of any medical or surgical condition. As surgeons refine surgical counseling to provide more accurate success estimates, baseline symptoms should be carefully assessed to ensure that the symptom burden warrants surgery and to evaluate the utility of addressing modifiable factors before surgery. The three risk factors associated with surgical failure and several baseline factors associated with worsening pelvic floor symptoms after surgery can be incorporated into surgical counseling. Improved counseling may better align patient goals and expectations with the reality of the surgical experience.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Authors' Data Sharing Statement

Will individual participant data be available (including data dictionaries)? *Yes.*

What data in particular will be shared? *De-identified participant data, data dictionary through the* Eunice Kennedy Shriver *National Institute of Child Health and Human Development, Data and Specimen Hub (DASH).*

What other documents will be available? *Data dictionary, case report forms.*

When will data be available (start and end dates)? *Data are available now and will continue to be made available through DASH.*

By what access criteria will data be shared (including with whom, for what types of analyses, and by what mechanism)? *Request* via *the DASH website.*

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Table 1.

Demographic, Baseline, and Perioperative Characteristics of the OPTIMAL and E-OPTIMAL Study Populations

Characteristic	OPTIMAL Total (n=374)	E-OPTIMAL Total (n=285)
Age (y)	57.2±10.9	57.2±10.8
Race		
White	315 (84.2)	238 (83.5)
Black	22 (5.9)	21 (7.4)
Asian	4 (1.1)	2 (0.7)
American Indian or Alaska Native	2 (0.5)	2 (0.7)
Other	31 (8.3)	22 (7.7)
Hispanic ethnic group	75 (20.1)	56 (19.6)
Vaginal deliveries	3.0±1.8	3.0±1.9
Cesarean deliveries	0.1±0.4	0.1±0.5
Menstrual status		
Premenopausal	106 (28.3)	82 (28.8)
Postmenopausal	246 (65.8)	188 (66.0)
Not sure	22 (5.9)	15 (5.3)
Currently using estrogen therapy		
Oral or patch	46 (12.3)	36 (12.6)
Vaginal	88 (23.5)	67 (23.5)
Current smoker	33 (8.8)	23 (8.1)
Diabetes mellitus	44 (12.0)	30 (10.8)
Connective tissue disease	5 (1.4)	5 (1.8)
Prior hysterectomy	100 (26.7)	74 (26.0)
Prior SUI surgery	13 (3.5)	10 (3.5)
Prior POP surgery	26 (7.0)	18 (6.3)
BMI (kg/m^2)	28.8±5.5	28.9±5.5
POP-Q stage		
2	144 (38.5)	107 (37.5)
3	212 (56.7)	166 (58.2)
4	18 (4.8)	12 (4.2)

Characteristic	OPTIMAL Total (n=374)	E-OPTIMAL Total (n=285)
Prolapse beyond the hymen		
Ba greater than 0	269 (71.9)	210 (73.7)
Bp greater than 0	73 (19.5)	54 (18.9)
C greater than 0	113 (30.3)	86 (30.3)
Baseline GH	4.7±1.2	4.7±1.2
Baseline PB	3.4±1.0	3.4±1.0
Baseline TVL	9.4±1.3	9.4±1.2
Concurrent anterior colporrhaphy	224 (59.9)	176 (61.8)
Concurrent posterior colporrhaphy or perineoplasty	190 (50.8)	146 (51.2)
Concurrent hysterectomy	271 (72.5)	210 (73.7)
Baseline sexual activity	197 (54.0)	144 (54.1)
Baseline SF36 limitation in physical activity (question 3) *		
Yes, limited a lot	214 (55.3)	157 (56.9)
Yes, limited a little	113 (29.2)	78 (28.3)
No, not limited at all	60 (15.5)	41 (14.9)
Clavien-Dindo classification (grade 3–5) †	1 (0.3)	0 (0.0)
Most distal point (cm)		
Anterior	2.1±2.2	2.2±2.2
Posterior	0.5±2.7	0.4±2.7
Apical	−0.9±3.5	−1.0±3.4
Regularly performs pelvic floor muscle exercises	80 (21.6)	62 (22.0)
Prior supervised pelvic floor muscle program	14 (3.8)	10 (3.6)
Concurrent TVT	371 (99.2)	284 (99.6)
Baseline POPDI score	123.8±68.6	122.3±68.7
Baseline UDI score	126.5±60.3	124.4±58.8
Baseline CRADI score	110.6±83.8	107.1±82.7
Pelvic muscle strength (Brink score)	7.9±2.0	8.0±2.0

OPTIMAL, Operations and Pelvic Muscle Training in the Management of Apical Support Loss trial; E-OPTIMAL, Extended trial; SUI, stress urinary incontinence; POP, pelvic organ prolapse; BMI, body mass index; POP-Q, pelvic organ prolapse quantification; Ba, most distal position of any part of the upper anterior vaginal wall; Bp, most distal position of any part of the upper posterior vaginal wall; C, a point on either the most distal edge of the cervix or the leading edge of the vaginal cuff; GH, genital hiatus; PB, perineal body; TVL, total vaginal length; SF-36, Medical Outcomes Study Questionnaire Short-Form 36; TVT, tension-free vaginal tape; POPDI, Pelvic Organ Prolapse Distress Inventory; UDI, Urinary Distress Inventory; CRADI, Colorectal-Anal Distress Inventory.

Data are mean±SD or n (%)

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[*] "Does your health now limit you in these activities? If so, how much (yes limited a lot, yes limited little, no not limited at all)."

[†] Clavien-Dindo classification refers to complications noted after the surgical intervention in the OPTIMAL trial. It is a rank of surgical complications by the therapy used to correct a specific complication: grade 3 requires surgical, endoscopic, or radiologic intervention; grade 4 is a life-threatening complication; grade 5 is death of a patient.

Table 2.

Results of Adjusted Models of Surgical Failure and Worsening of Pelvic Floor Symptoms by the Minimal Clinically Important Difference

Modeled Outcomes and Risk Factors Included in Each Model	aOR	95% CI
Adjusted model of surgical failure		
Hispanic ethnic group (ref=non-Hispanic)	1.92	1.17–3.15
Currently using estrogen therapy: vaginal (ref=not using vaginal estrogen therapy)	0.82	0.51–1.34
Anterior: most distal point *	1.08	0.97–1.19
Baseline GH *	1.14	0.96–1.35
Baseline PB *	1.34	1.09–1.63
Baseline POPDI score *	1.16	1.05–1.28
Adjusted model of POPDI score worsening † (MID)		
White race (ref=non-White)	0.61	0.24–1.60
BMI (kg/m^2) *	1.03	0.96–1.10
Baseline POPDI score *	0.75	0.60–0.94
Adjusted model of UDI score worsening † (MID)		
Vaginal deliveries *	1.26	1.10–1.44
Baseline UDI score *	0.86	0.80–0.93
Adjusted model of CRADI worsening † (MID)		
Age (y) *	1.03	1.01–1.05
Baseline CRADI score *	0.95	0.92–0.98

aOR, adjusted odds ratio; ref, reference; GH, genital hiatus; PB, perineal body; POPDI, Pelvic Organ Prolapse Distress Inventory; MID, minimal clinically important difference; UDI, Urinary Distress Inventory; CRADI, Colorectal Anal Distress Inventory.

Adjusted model of surgical failure includes timepoint, Hispanic ethnic group, currently using estrogen therapy, most distal anterior point, baseline GH, baseline PB, and baseline POPDI score.

Adjusted model of POPDI includes timepoint, White race, BMI, and baseline POPDI score.

Adjusted model of UDI includes timepoint, vaginal deliveries, and baseline UDI score.

Adjusted model of CRADI includes timepoint, age, and baseline CRADI score.

$P<.01$ for overall effect of time (Pr>.F) in all outcomes.

* Odds ratios for continuous predictor variables are for a 1-cm increase for anatomic measures, 1-unit increase in BMI, 1-year increase in age, and MID for POPDI, UDI, and CRADI.

† Worsening defined as increases in score at least as large as the MID of 34.3 for POPDI and 11 for UDI and CRADI.

Table 3.

Results of Adjusted Models of Changes From Baseline in Pelvic Floor Symptom Scale Scores

Modeled Scales and Risk Factors Included in Each Model	Beta	95% CI
Adjusted model of POPDI score (change from baseline)		
Hispanic race–ethnicity (ref=White)	11.58	4.80–18.36
Other race–ethnicity (ref=White)	22.22	13.27–31.17
Maximum of most distal anterior, apical, or posterior point at baseline	−1.02	−2.26 to 0.22
SF-36 physical limitation * “a little” (ref=“not limited at all”)	−0.10	−8.19 to 8.00
SF-36 physical limitation * “a lot” (ref=“not limited at all”)	10.32	2.94–17.70
BMI	0.09	−0.40 to 0.57
Baseline PB	4.35	1.84–6.86
Baseline POPDI score	−0.63	−0.66 to −0.59
Adjusted model of UDI score (change from baseline)		
Hispanic race–ethnicity (ref=White)	11.12	−0.26 to 22.49
Other race–ethnicity (ref=White)	13.10	−1.41 to 27.61
Menstrual status unsure (ref=premenopausal)	19.59	0.44–38.75
Menstrual status postmenopausal (ref=premenopausal)	9.33	−0.75 to 19.40
Sexually active at baseline	−7.36	−16.65 to 1.92
No. of vaginal deliveries	2.31	−0.03 to 4.66
Baseline PB	6.30	2.09–10.51
Baseline UDI score	−0.74	−0.81 to −0.67
Adjusted model of CRADI score (change from baseline)		
POP-Q stage at baseline (ref=stage 2)	2.31	−9.05 to 13.67
SF-36 physical limitation * “a little” (ref=“not limited at all”)	−7.48	−23.08 to 8.11
SF-36 physical limitation * “a lot” (ref=“not limited at all”)	8.83	−5.33 to 22.98
Age at randomization (y)	0.23	−0.28 to 0.74
Baseline PB	3.66	−1.20 to 8.51
Baseline TVL	−2.97	−7.02 to 1.08
Baseline Brink score	−1.60	−4.11 to 0.91
Baseline CRADI score	−0.61	−0.67 to −0.55

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POPDI, Pelvic Organ Prolapse Distress Inventory; ref, reference; SF-36, Medical Outcomes Study Questionnaire Short-Form 36; BMI, body mass index; PB, perineal body; UDI, Urinary Distress Inventory; CRADI, Colorectal-Anal Distress Inventory; POP-Q, pelvic organ prolapse quantification; TVL, total vaginal length.

Adjusted model of POPDI score includes timepoint; Hispanic race–ethnicity (vs white); other race (vs white); maximum of most distal anterior, apical, or posterior point at baseline; SF-36 physical limitation; BMI; baseline PB; and baseline POPDI score.

Adjusted model of UDI score includes timepoint, Hispanic race–ethnicity (vs white), other race (vs white), menstrual status, sexually active at baseline, number of vaginal deliveries, baseline PB, and baseline UDI score.

Adjusted model of CRADI score includes timepoint, POP-Q stage at baseline, SF-36 physical limitation, age in years at randomization, baseline PB, baseline TVL, baseline Brink score, and baseline CRADI score.

Brink score is a digital assessment of pelvic floor muscle strength.

$P<.01$ for overall effect of time (Pr>.F) in all outcomes.

Change from baseline was calculated as post–subscale score minus pre–subscale score. A post–subscale score that was lower than the pre–subscale score indicates improvement. A negative Beta coefficient indicates that if the risk factor is present (categorical) or increases (continuous or ordinal), the risk factor is associated with improvement.

*Question 3: “Does your health now limit you in these activities? If so, how much (yes limited a lot, yes limited a little, no not limited at all).”

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