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Standard Restrictions vs Expedited Activity After Pelvic Organ Prolapse Surgery
A Randomized Clinical Trial

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IMPORTANCE Restrictions on postoperative activity following pelvic organ prolapse (POP) surgery are not evidence based. Nonetheless, many pelvic surgeons place lifting and activity restrictions on patients following surgery.

OBJECTIVE To evaluate whether expedited activity results in noninferior anatomic and symptomatic outcomes compared with standard activity restrictions after POP surgery.

DESIGN, SETTING, AND PARTICIPANTS This randomized noninferiority clinical trial included patients undergoing vaginal or laparoscopic apical reconstructive surgery for POP between July 1, 2020, and October 31, 2021, at a single academic tertiary referral center in Durham, North Carolina. Anatomic outcomes were assessed by masked examiners, and subjective outcomes were assessed via validated surveys, both completed at 3 months postoperatively. Patients meeting minimum physical activity criteria with at least stage II bothersome POP were eligible. A total of 218 patients were approached, of whom 123 were randomly assigned and 107 had complete outcome data and were included in the analysis.

INTERVENTIONS Patients were randomly assigned to receive standard restrictions vs expedited postoperative activity instructions.

MAIN OUTCOMES AND MEASURES The anatomic coprimary outcome was maximum anatomic POP support loss (SLmax), which is the most distal point of pelvic organ support loss according to the Pelvic Organ Prolapse Quantification System (noninferiority margin, 1.0 cm). The symptomatic coprimary outcome was the Pelvic Organ Prolapse Distress Inventory (POPDI) symptom score (noninferiority margin, 34.3 points). Differences between outcomes were assessed using linear regression models controlling for baseline SLmax and POPDI, respectively.

RESULTS Of 123 participants randomized, 107 had complete 3-month outcome data and were included in the analysis. Mean (SD) age was 62.8 (10.1) years. At 3 months, mean (SD) SLmax was −1.7 (1.4) cm in the expedited group and −1.5 (1.4) cm in the standard group (P = .44). After adjusting for baseline SLmax, the mean maximum support loss was 0.18 cm higher within the vaginal canal in the expedited group (95% CI, −0.68 to 0.33 cm). The coprimary outcome of POPDI score was a mean (SD) 23.7 (41.8) points in the expedited group vs 25.7 (39.3) points in the standard group (P = .80). After adjusting for baseline scores, mean POPDI scores were 5.79 points lower in the expedited group (95% CI, −20.41 to 8.84).

CONCLUSIONS AND RELEVANCE The findings demonstrate that expedited activity after prolapse surgery results in noninferior anatomic and symptomatic prolapse outcomes. It is reasonable to instruct patients undergoing minimally invasive prolapse surgery to resume physical activities ad lib postoperatively.

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Visual Abstract

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Supplemental content

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Activity recommendations and lifting restrictions after gynecologic surgery are based on tradition and anecdote.[1] Despite a paucity of evidence, 82% to 86% of gynecologic surgeons recommend postoperative lifting restrictions, with one-half recommending a maximum of 10 lb.[2]

For pelvic organ prolapse (POP) surgery, lifting restrictions are primarily based on theoretical avoidance of intra-abdominal pressure (IAP) compromising a recent reconstruction. However, in a study of healthy volunteers, daily physiologic events, such as Valsalva maneuver and coughing, generated more IAP than lifting weight off the floor.[3,4] Such evidence challenges the notion that avoiding weight-bearing activities is protective.

Unnecessarily restricting postoperative activity may not be benign. The arbitrary limitation of patients' postoperative activity level could influence postoperative deconditioning, weight gain, and venous thromboembolism risk. In an older surgical population, artificially limiting mobility may adversely affect postoperative recovery trajectories.

The abdominal surgery literature regarding postoperative activity is limited. A recent systematic review of activity restrictions after abdominal surgery identified only 2 randomized trials.[5-7] The first found that randomizing women undergoing prolapse surgery to receive either liberal or restrictive postoperative instructions did not have an effect on objective or subjective measures of activity.[6] Another randomized trial of restrictive vs liberal activity recommendations following POP surgery found no differences in patient satisfaction at 3 months and 1 year postoperatively.[7,8] Given the trial design as a superiority study, and caution in the interpretation of nonsignificant secondary outcomes in such trials, the effect of liberal activity on POP outcomes after surgery remains unclear.[7]

To justify practice change, patients and surgeons need convincing evidence that liberalized activity does not compromise outcomes or increase complications. Therefore, the objective of the current study was to determine whether expedited resumption of postoperative activity is noninferior to standard activity restrictions with respect to 3-month anatomic and symptomatic outcomes. We hypothesized that immediate resumption of physical activities as tolerated after prolapse surgery would result in noninferior anatomic support and symptomatic outcomes compared with standard restrictions.

Key Points

Question Are expedited instructions noninferior to standard activity instructions after minimally invasive surgery for pelvic organ prolapse?

Findings In this randomized clinical trial that included 107 women, patients who received liberal activity instructions experienced noninferior anatomic and symptomatic outcomes at 3 months following apical prolapse surgery.

Meaning The findings demonstrate that it is reasonable to instruct patients to resume activities ad lib after prolapse surgery, while reassuring patients that resuming physical activity quickly will not result in worse anatomic or symptomatic outcomes.

Methods

This randomized noninferiority clinical trial included patients undergoing apical POP surgery within 1 academic health system in Durham, North Carolina, between July 1, 2020, and November 30, 2021. Ethics approval was obtained from the Duke University institutional review board. All participants provided written informed consent. This study followed the Consolidated Standards of Reporting Trials (CONSORT) reporting guideline. The trial protocol and statistical analysis plan are in Supplement 1.

Patients were considered if they had stage II to IV POP, had bothersome symptoms, were English-speaking, had planned surgery for apical prolapse correction occurring at least 7 days from randomization, and were willing to follow up at 3 months for in-office examinations. To identify a physically active population at baseline and screen for eligibility, we additionally used 2 physical function questions from the National Health and Nutrition Examination Survey: (1) Do you have difficulty walking 2 to 3 blocks? and (2) Do you have difficulty walking up 10 stairs?[9] Participants responding no difficulty to both screening questions were eligible. Including physically inactive patients would have been biased toward noninferiority, which was why these thresholds were set. Exclusion criteria were enrollment in another POP research study, concomitant nonurogynecologic surgery, additional planned surgery within 3 months of POP surgery, or other anticipated treatment that could result in prolonged inactivity. Participants were screened at their preoperative clinic visit or via a recruitment phone call. Patients meeting inclusion and exclusion criteria were then randomized to 1 of 2 treatment groups, as follows: (1) standard instructions (no heavy lifting >10 lb for 6 weeks, return to work after 2 weeks for sedentary work and after 6 weeks for manual labor) or (2) expedited instructions (no restrictions, resume activities and work as soon as able). Participants in both groups were instructed to avoid sexual activity until the 6-week postoperative visit.

Participants were randomized 1:1 to standard or expedited activity restrictions using a computerized randomization scheme with a block size of 4 generated by the statistician (T.T.). Stratification was performed based on concomitant hysterectomy and route of surgery (laparoscopic or vaginal). Participants undergoing a laparoscopic approach received robotic-assisted laparoscopic sacrocolpopexy with mesh. Vaginal approaches included native tissue or graft-augmented repairs. Randomization was performed by masked study personnel (M.O. and a clinical research coordinator). Allocation sequence was concealed from all study personnel involved in randomization. Surgeons and outcome assessors (N.S., M.B., 5 additional surgeons, and 2 additional outcome assessors) were not informed of treatment allocation until completion of study participation.

Enrolled patients completed baseline symptom and health-related quality of life questionnaires, which consisted of the

Activities Assessment Scale; Pelvic Floor Distress Inventory-20; Pelvic Organ Prolapse Distress Inventory-16 (POPDI); Pelvic Floor Impact Questionnaire-7; and the Patient-Reported Outcomes Measurement System short form subscales of physical function, anxiety, depression, fatigue, satisfaction with social role, and pain interference.[10-15] Data on race and ethnicity were abstracted from the electronic health record to aid in assessing the generalizability of the study population. Preoperative physical function was assessed with a 2-minute step test and chair stand test, which was performed either in person or remotely via video visit.[16] For the chair stand test, the participant stands up from a chair as many times as possible over 30 seconds.[16] For the 2-minute step test, the participant walks in place for 2 minutes, and the number of times their right knee is lifted is recorded.[16]

Participants received their instructions at the time of their baseline research visit. They were also given an ActiGraph wGT3X-BT accelerometer (ActiGraph, LLC), which was to be worn for at least 4 days prior to surgery and until 6 weeks postoperatively. Participants wore the accelerometer on the nondominant wrist during waking hours, and objective activity measures were continuously recorded. Postoperative pain medication was not standardized; however, standard practice was to prescribe ten 5-mg tablets of oxycodone upon discharge, and exceptions were infrequent.

At 2 weeks after surgery, patients were reminded via telephone to charge the accelerometer, and the number of opioid pills originally prescribed and the number of pills remaining were recorded. Participants returned 3 months after surgery to undergo a standard POP Quantification System (POPQ) examination by an examiner unaware of randomization status and to complete follow-up questionnaires. Time to return to work was also assessed, and objective physical function measures were repeated. Postoperative complications were abstracted from the patient medical record.

As anatomic and symptomatic outcomes are considered equally important for assessments of prolapse, we used coprimary anatomic and symptomatic outcomes. The anatomic primary outcome was maximum anatomic POP support loss (SLmax), as measured by the most distal point of pelvic organ support loss. The SLmax value is a previously described continuous summary score to measure anatomic prolapse and has been strongly correlated with POPQ ordinal staging while demonstrating greater responsiveness to change.[17] The symptomatic primary outcome was the 16-item POPDI, which is scored from 0 to 300, with higher scores indicating more symptomatic distress.[15] A conservative estimate of the minimal clinically important difference for the POPDI has been previously reported to be 34.3 points.[18,19]

Secondary outcomes included Pelvic Floor Distress Inventory-20, Pelvic Floor Impact Questionnaire-7, Patient-Reported Outcomes Measurement System subscale scores, and the Patient Global Impression of Improvement. Preoperative and postoperative physical activity recovery time, defined a priori as the postoperative day at which the participant resumed 90% of baseline activity levels based on accelerometer data,[20,21] was compared between groups. Physical function was objectively measured with the 2-minute step test[22] and chair stand test[23] at the 3-month postoperative visit and subjectively measured with the Activities Assessment Scale questionnaire and time to return to work.

Sample Size Estimate

A priori sample size estimation determined that 100 participants would allow for 80% power to assess a noninferiority margin of 1 cm of SLmax, with an SD of 1.2 cm and an α of .025.[17] A noninferiority threshold of a 1-cm difference was chosen because the investigative team felt this to be a clinically relevant change, and prior research has shown that the smallest discernable difference in POPQ measurements is 1.0 cm for the apex (point C) and 0.5 cm for other measurements.[24] This sample size also allowed assessment of noninferiority of the coprimary outcome POPDI using a noninferiority margin of 34.3 points between groups, with an SD of 68 points and an α of .025. Accounting for 15% attrition, we planned to randomize 118 participants for the study.

Statistical Analysis

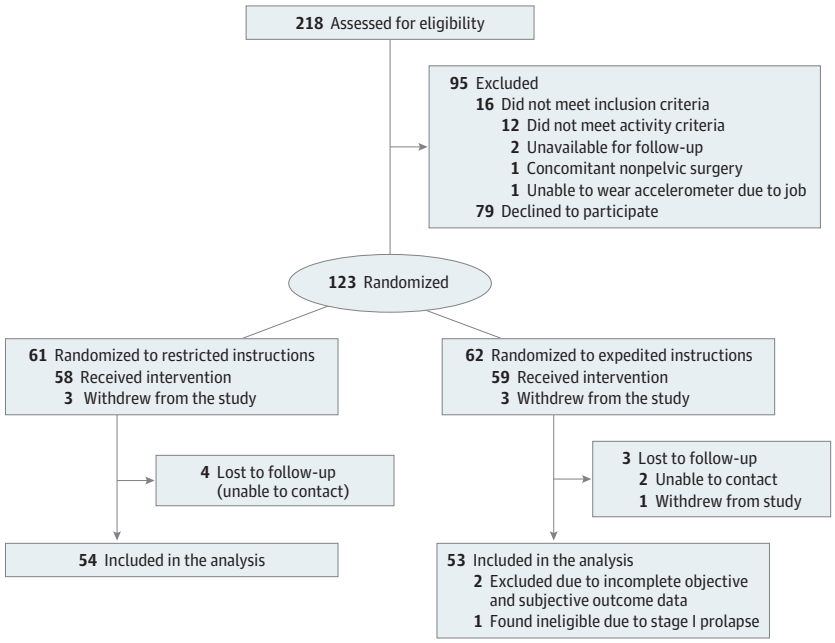
Participants' demographic and baseline characteristics were summarized using descriptive statistics. To assess for noninferiority of each of the coprimary outcomes, differences between the outcomes of the 2 randomized groups were assessed using linear regression models controlling for baseline SLmax or POPDI. If the upper limit of the 95% CI for the mean difference in the expedited instructions (standard instructions being the referent group) did not cross the noninferiority margin, the expedited instructions would be deemed noninferior. If the residuals of either primary outcome were not normally distributed, sensitivity analyses were performed using 10 000 bootstrapped samples to estimate the 95% bias-corrected CIs of the independent variable. The primary analysis was performed per protocol to avoid biasing toward noninferiority. An intention-to-treat analysis was also performed.

Secondary outcomes were compared between groups using 2-sample *t* tests with equal variance, Wilcoxon rank sum tests for continuous outcomes, or χ^2 or Fisher exact tests for categorical outcomes. Two-sided tests at $\alpha = .05$ were used for the secondary outcomes. All analyses were performed using SAS, version 9.4 statistical software (SAS Institute Inc).

Results

Between July 1, 2020, and October 31, 2021, 218 patients were approached for participation. Sixteen were ineligible, mostly due to an inability to meet minimum activity thresholds. A total of 123 participants were randomized. (**Figure 1**) Three from each group withdrew after randomization prior to surgery. One additional patient from the expedited activity group withdrew after surgery. One patient was discovered after randomization and study completion to have stage I prolapse and was excluded from analysis. A total of 107 patients completed 3-month assessments until February 2022 at a mean (SD) of 12.7 (2.1) weeks after surgery and were included in the primary analysis. The 8 participants (4 from each group) with missing data at 3 months were considered to be missing completely at ran-

Figure 1. Participant Flow Diagram



dom and assumed not related to activity assignment. Baseline characteristics of all randomized participants were not significantly different from those with complete follow-up data (eTable 1 in Supplement 2).

The mean (SD) age of participants was 62.8 (10.1) years, mean (SD) body mass index was 28.0 (6.0) (as measured by weight in kilograms divided by height in meters squared), and the majority of participants (87 [81.3%]) were postmenopausal and White (82 [76.6%] vs 22 [20.6%] African American or Black, 1 [0.9%] Hispanic or Latinx, and 2 [1.9%] not reported). Overall demographic and clinical characteristics were well balanced between the 2 groups, with the exception of history of prior urogynecologic surgery (**Table 1**).[22,23] Of the 44 (41.1%) participants who reported presently working full or part time, 7 (15.9%) reported heavy physical workload.

A total of 57 participants (53.2%) underwent vaginal repair, and 48 (44.9%) underwent robotic-assisted laparoscopic mesh sacrocolpopexy (**Table 2**). Concomitant procedures were not significantly different between groups. At 2 weeks, there was a median of 5 (IQR, 0-10) opioid pills remaining out of a median of 10 (IQR, 6-10) prescribed pills, with no significant differences between groups.

The mean (SD) coprimary anatomic outcome of SLmax at 3 months was −1.7 (1.4) cm in the expedited group and −1.5 (1.4) cm in the standard activity group at 3 months (**Table 3**). In the primary linear regression analysis, when controlling for baseline SLmax, the 95% CI for the mean difference in the SLmax (−0.18 cm) of the expedited instructions group ranged from −0.68 to 0.33 cm. Given that the prespecified noninferiority margin was 1.0 cm, the adjusted mean difference in SLmax between groups supports the noninferiority of expedited activity instructions (**Figure 2**; eTable 2 in Supplement 2).

The coprimary subjective outcome of POPDI score was a mean (SD) of 23.7 (41.8) points at 3 months in the expedited group vs 25.7 (39.3) points in the standard activity group (Table 3). In a linear regression analysis, when controlling for baseline POPDI score, the 95% CI for the mean difference in POPDI score (−5.79 points) ranged from −20.41 to 8.84 points. Given that the CI of the adjusted mean difference in POPDI scores did not approach our noninferiority margin of 34.3, analysis of the symptomatic outcome also supports the noninferiority of expedited instructions (Figure 2; eTable 2 in Supplement 2).

Secondary outcomes, including patient-reported measures of pelvic floor symptoms, condition-specific, and generic health-related quality of life measures, were not significantly different between groups (Table 3). Most patients (98 [92.4%]) reported being either much better or very much better on the Patient Global Impression of Improvement questionnaire following their surgery, with no differences between groups.

Despite having similar subjective and objective levels of physical function at baseline, patients in the expedited group had significantly higher levels of baseline activity (median, 62 [IQR, 46-117] vs 37 [IQR, 23-75] moderate to vigorous physical activity [MVPA] minutes per day; $P = .003$) (eTable 3 in Supplement 2). However, after surgery, the 2 groups did not have significant differences in 90% recovery time, with both groups taking a median of 9 (IQR, 4-20) days to recover 90% of their baseline preoperative activity levels ($P = .79$) (eFigure in Supplement 2). In a Cox proportional hazards model, the hazard of achieving baseline activity did not significantly differ between the 2 groups when adjusted for baseline level of activity or history of prior POP or stress urinary incontinence surgery (hazard ratio, 0.83; 95% CI, 0.53-1.31).

Table 1. Baseline Participant Characteristics and Survey Data by Study Arm

	No. (%)		
	Standard activity (n = 54)	Expedited activity (n = 53)	Total population (n = 107)
Age, mean (SD), y	63.8 (8.9)	61.8 (11.3)	62.8 (10.1)
Race and ethnicity			
African American or Black	11 (20.4)	11 (20.8)	22 (20.6)
Hispanic or Latinx	1 (1.9)	0 (0.0)	1 (0.9)
White	41 (75.9)	41 (77.4)	82 (76.6)
Not reported	1 (1.9)	1 (1.9)	2 (1.9)
Body mass index[a]	27.1 (5.6)	28.8 (6.2)	28.0 (6.0)
Postmenopausal	45 (83.3)	42 (79.2)	87 (81.3)
Vaginal parity, median (IQR)	2 (2-3)	2 (1-3)	2 (2-3)
Use of estrogen therapy	11 (20.4)	7 (13.2)	18 (16.8)
Diabetes	6 (11.1)	5 (9.4)	11 (10.3)
Smoking	3 (5.6)	3 (5.7)	6 (5.6)
Prior prolapse surgery	2 (3.7)	10 (19.2)	12 (11.3)
Prior SUI surgery	2 (3.7)	6 (11.5)	8 (7.5)
Prior hysterectomy	14 (25.9)	16 (30.2)	30 (28.0)
Employment			
Full time	19 (35.2)	13 (24.5)	32 (29.9)
Part time	6 (11.1)	6 (11.3)	12 (11.2)
Not currently employed	29 (53.7)	34 (64.2)	63 (58.9)
Current physical workload			
No. of participants analyzed	25	19	44
Light	10 (40.0)	14 (73.7)	24 (54.5)
Moderate	10 (40.0)	3 (15.8)	13 (29.6)
Heavy	5 (20.0)	2 (10.5)	7 (15.9)
AAS score	89.0 (11.4)	86.6 (14.2)	87.8 (12.9)
2MST, median (IQR), No. of steps[b]	86 (69-99)	80 (70-100)	85.5 (69.5-100)
Missing	3 (5.6)	0	3 (2.8)
Chair stand test, median (IQR), No. of sit-to-stand intervals[c]	13 (11-16)	13 (10-15)	13 (11-16)
Missing	3 (5.6)	0	3 (2.8)
Baseline POPQ measurements, cm, mean (SD)			
Anterior wall[d]			
Aa	1.6 (1.7)	1.4 (1.6)	1.5 (1.7)
Ba	2.7 (2.2)	2.5 (2.2)	2.6 (2.2)
C (cervix or cuff)	−0.8 (4.2)	−0.9 (4.3)	−0.8 (4.2)
Posterior wall[e]			
Ap	−1.3 (1.8)	−1.3 (1.7)	−1.3 (1.7)
Bp	−0.3 (2.9)	−0.6 (2.8)	−0.4 (2.8)
GH (genital hiatus)	4.5 (1.2)	4.8 (1.2)	4.7 (1.2)
PB (perineal body)	3.1 (0.7)	3.2 (0.9)	3.2 (0.8)
SLmax	3.0 (1.8)	2.9 (1.8)	3.0 (1.8)
POPQ stage			
II	11 (20.4)	12 (22.6)	23 (21.5)
III	39 (72.2)	36 (67.9)	75 (70.1)
IV	4 (7.4)	5 (9.4)	9 (8.4)
POPDI score, mean (SD)	97.1 (57.7)	116.2 (71.0)	106.6 (65.0)
PFDI-20 score, mean (SD)	99.8 (52.7)	109.1 (57.4)	104.4 (55.0)

(continued)

Table 1. Baseline Participant Characteristics and Survey Data by Study Arm (continued)

	No. (%)		
	Standard activity (n = 54)	Expedited activity (n = 53)	Total population (n = 107)
PFIQ-7 score, mean (SD)	49.1 (51.6)	83.5 (73.7)	66.1 (65.5)
PROMIS score, mean (SD)			
Pain interference	48.9 (9.9)	52.5 (10.9)	50.7 (10.5)
Depression	45.6 (9.2)	48.4 (9.2)	47 (9.2)
Fatigue	50.3 (5.6)	53.5 (6.6)	51.9 (6.3)
Satisfaction with social roles	52.5 (11.7)	45.0 (9.8)	48.9 (11.4)
Physical function	48.8 (7.3)	48.7 (7.9)	48.8 (7.6)
Anxiety	45.5 (9.4)	47.6 (9.9)	46.6 (9.6)

Abbreviations: 2MST, 2-Minute Step Test; AAS, Activities Assessment Scale (0-100, higher scores indicate better physical function); PFDI-20, Pelvic Floor Distress Inventory-20 (0-300, higher scores indicate greater symptom distress); PFIQ-7, Pelvic Floor Impact Questionnaire-7 (0-300, higher scores indicate greater effect of pelvic floor symptoms on quality of life); POPDI, 16-item Pelvic Organ Prolapse Distress Inventory (0-300, higher scores indicate greater symptom distress); POPQ, Pelvic Organ Prolapse Quantification System; PROMIS, Patient-Reported Outcomes Measurement Information System (T-scores presented, higher scores represent more of the concept being measured); SLmax, maximum anatomic pelvic organ prolapse support loss; SUI, stress urinary incontinence.

[a] As measured by weight in kilograms divided by height in meters squared.

[b] The normative mean for the 2MST among community-residing adults is 83 steps.[22]

[c] The normative mean for the chair stand test among community-residing adults is 12.7 intervals.[23]

[d] Aa is the point located at the midline of the vagina 3 cm proximal to the external urethral meatus; by definition, can range from 3 cm proximal to 3 cm distal to the hymen (−3 to +3). Ba is the most distal point of the anterior vaginal wall.

[e] Ap is the point located at the posterior midline of the vagina 3 cm proximal from the hymen; by definition, can range from 3 cm proximal to 3 cm distal to the hymen (−3 to +3). Bp is the most distal point of the posterior vaginal wall.

Table 2. Surgeries Performed by Study Arm

	No. (%)		
Surgery	Standard activity (n = 54)	Expedited activity (n = 53)	Total population (n = 107)
Apical procedures			
Sacrocolpopexy[a]	24 (44.4)	24 (45.3)	48 (44.9)
USLS	14 (25.9)	19 (35.8)	33 (30.8)
SSLF	9 (16.7)	7 (13.2)	16 (15.0)
SSLF hysteropexy[b]	5 (9.3)	2 (3.8)	7 (6.5)
Ileococcygeus	1 (1.9)	0 (0.0)	1 (0.9)
No apical procedure[c]	1 (1.9)	1 (1.9)	1 (0.9)
Concomitant procedures			
Anterior colporrhaphy	26 (48.1)	26 (49.1)	52 (48.6)
Posterior colporrhaphy	21 (38.9)	26 (49.1)	47 (43.9)
Midurethral sling	21 (38.9)	22 (41.5)	43 (40.2)
Hysterectomy	34 (63.0)	36 (67.9)	70 (65.4)

Abbreviations: SSLF, sacrospinous ligament fixation; USLS, uterosacral ligament suspension.

[a] Performed with robotic-assisted laparoscopy using synthetic polypropylene mesh.

[b] With or without graft.

[c] Apical procedure planned but not performed on day of surgery.

Median return-to-work time was 28 (IQR, 11-45) days in the expedited group and 34 (IQR, 7-44) days in the standard activity group (P = .58) (eTable 4 in Supplement 2). Postoperative subjective and objective measures of physical function were not significantly different between groups (eTable 5 in Supplement 2). There were no differences in postoperative complications (eTable 6 in Supplement 2).

Discussion

Expedited postoperative activity instructions after prolapse surgery resulted in noninferior symptomatic and anatomic outcomes at 3 months. There were no significant differences in accelerometer-based recovery time, and both groups recovered to 90% of their baseline activity rapidly. Overall subjective and objective measures of physical function, symptom severity, and quality-of-life measures were also not significantly different.

Our findings are consistent with the aforementioned randomized superiority trial by Mueller et al[7] of restrictive vs liberal activity recommendations following prolapse surgery. Separate from trial design, our study population differs, as only 45% underwent mesh sacrocolpopexy compared with 61% in the Mueller et al study. As such, our findings add generalizability for practices in which vaginal repair is commonly performed.

We did not find significant differences in time to return to work among employed participants. This finding contrasts with a prior Danish multicenter prospective cohort study of patients undergoing inguinal herniorrhaphy, where median time taken off work was 7 days in the shortened convalescence

Table 3. Three-Month Pelvic Organ Prolapse Quantification System (POPQ) Scores and Symptom Surveys

	Mean (SD)[a]				
	Standard activity (n = 54)	Expedited activity (n = 53)	Total population (n = 107)	*P* value	Adjusted mean difference (95% CI)[b]
Coprimary outcome measures					
SLmax (objective), cm	−1.5 (1.4)	−1.7 (1.4)	−1.6 (1.4)	.44	−0.26 (−0.79 to 0.26)
POPDI score (subjective), points	25.7 (39.3)	23.7 (41.8)	24.7 (40.4)	.80	−3.14 (−18.29 to 12)
Other measures					
POPQ measurements, cm					
Anterior wall[c]					
Aa	−2.1 (1.1)	−2.1 (1.2)	−2.1 (1.2)	.80	NA
Ba	−2.1 (1.1)	−2.1 (1.2)	−2.1 (1.2)	.83	NA
C (cervix or cuff)	−7.2 (1.4)	−7.5 (1.3)	−7.3 (1.4)	.34	NA
Posterior wall[d]					
Ap	−2.7 (0.8)	−2.6 (0.9)	−2.7 (0.8)	.46	NA
Bp	−2.7 (0.8)	−2.6 (0.9)	−2.7 (0.8)	.46	NA
GH (genital hiatus)	3.2 (1.2)	3.4 (1.1)	3.3 (1.1)	.36	NA
PB (perineal body)	3.8 (0.9)	3.7 (0.8)	3.8 (0.9)	.60	NA
TVL (total vaginal length)	8.5 (1.4)	8.7 (1.4)	8.6 (1.4)	.52	NA
Validated questionnaires					
PFDI-20					
Total score	27.4 (31.8)	24.7 (36.1)	26.1 (33.9)	.68	NA
Urinary subscale	12.0 (16.4)	10 (13.9)	11 (15.2)	.51	NA
Prolapse subscale	4.9 (7.9)	6.4 (14.6)	5.6 (11.7)	.52	NA
Colorectal subscale	10.5 (18.2)	8.3 (12.7)	9.4 (15.7)	.47	NA
PFIQ-7					
Total score	14.7 (30.6)	16.3 (34.7)	15.5 (32.6)	.80	NA
Urinary subscale	8.4 (19.8)	7.9 (19.3)	8.2 (19.5)	.89	NA
Prolapse subscale	2.3 (8.4)	4.3 (12.4)	3.3 (10.6)	.35	NA
Colorectal subscale	4.1 (12.7)	4.1 (11.5)	4.1 (12.1)	.97	NA
PROMIS score					
Pain interference	42.2 (3.7)	43 (5.7)	42.6 (4.8)	.42	NA
Depression	42.0 (7.4)	41.5 (6.8)	41.7 (7.1)	.68	NA
Fatigue	47.7 (4.8)	47.5 (5.3)	47.6 (5.1)	.83	NA
Satisfaction with social roles	55.7 (9.1)	55.3 (8.6)	55.5 (8.8)	.82	NA
Physical function	54.2 (7.8)	53.8 (8.8)	54.0 (8.3)	.84	NA
Anxiety	43.7 (8.6)	43.9 (8.1)	43.8 (8.3)	.89	NA

Abbreviations: NA, not applicable; PFDI-20, Pelvic Floor Distress Inventory-20 (0-300, higher scores indicate greater symptom distress); PFIQ-7, Pelvic Floor Impact Questionnaire-7 (0-300, higher scores indicate greater effect of pelvic floor symptoms on quality of life; subscales graded 0-100); POPDI, 16-item Pelvic Organ Prolapse Distress Inventory (0-300, higher scores indicate greater symptom distress; subscales graded 0-100); POPQ, Pelvic Organ Prolapse Quantification System; PROMIS, Patient-Reported Outcomes Measurement Information System (T-scores presented, higher scores represent more of the concept being measured); SLmax, maximum anatomic pelvic organ prolapse support loss.

[a] The *t* test was used for normally distributed continuous variables, and Wilcoxon rank sum was used for nonnormally distributed data.

[b] Adjusted for baseline SLmax or POPDI, respectively, and history of prior prolapse or anti-incontinence surgery.

[c] Aa is the point located at the midline of the vagina 3 cm proximal to the external urethral meatus; by definition, can range from 3 cm proximal to 3 cm distal to the hymen (−3 to +3). Ba is the most distal point of the anterior vaginal wall.

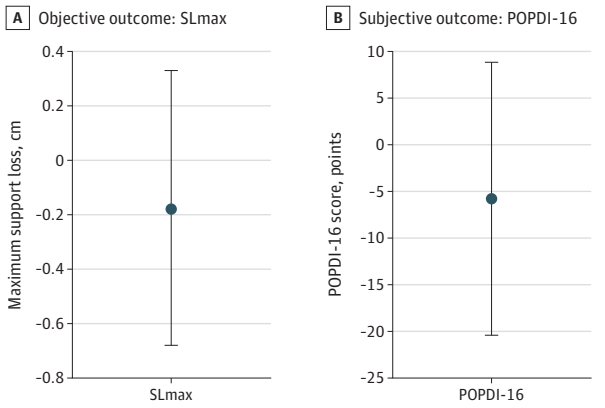
[d] Ap is the point located at the posterior midline of the vagina 3 cm proximal from the hymen; by definition, can range from 3 cm proximal to 3 cm distal to the ymen (−3 to +3). Bp is the most distal point of the posterior vaginal wall.

group.[25] We did identify a trend toward quicker return to work in the expedited activity group, though this analysis is considered exploratory because it was not sufficiently powered due to the low numbers of employed participants. There were overall few numbers of patients reporting heavy physical workloads. Therefore, further research is needed to confirm the safety of shortened convalescence for heavy physical work.

Our study adds important longitudinal data in that our population took a median of 9 days to recover 90% of their baseline accelerometer-based activity levels after surgery. A previous trial similarly did not find significantly different levels of relative postoperative activity between patients who were randomized to receiving liberal vs restricted instructions after prolapse surgery.[6] However, this study reported MVPA minutes in 3-day time frames at baseline and 2 weeks and 6 weeks postoperatively rather than longitudinally. We also observed significantly faster rates of recovery time than were observed by Collins et al,[21] where no participants undergoing abdominal or minimally invasive sacrocolpopexy recovered 90% of baseline activity by 14 days after surgery. Notably, all patients in the study by Collins et al[21] were provided restrictive instructions, and a minimum threshold of physical activity was not used as an inclusion criterion.

Our study participants' daily MVPA minutes are significantly higher than published normative data.[26] Our study intentionally screened for active participants, and patients who elected to participate may have biased toward a more active population. There is variability inherent to wrist-worn relative to waist-worn accelerometers, particularly if participants engage in activities that involve use of the upper extremities, which may overestimate activity. Wrist-worn accelerometers were chosen due to improved compliance and

Figure 2. Maximum Anatomic Pelvic Organ Prolapse Support Loss (SLmax) and 16-Item Pelvic Organ Prolapse Distress Inventory-16 (POPDI) Outcomes at 3 Months



Noninferiority margins (NIMs) of objective outcome vs subjective outcome at 3 months are shown. The horizontal lines indicate adjusted (for baseline SLmax or POPDI score) 95% CIs of mean difference, with standard activity group being the reference group. A priori NIMs are indicated for SLmax (1 cm) and POPDI (34.3 points).

overall good correlation with waist-worn accelerometry.[27] Therefore, our data should be interpreted to inform within-person differences in activity trends, and caution is warranted in generalizing the absolute number of MVPA minutes.

Strengths and Limitations

The strength of our study lies in its use of a randomized controlled noninferiority design. We also used relevant primary anatomic and symptomatic measures, which are equally important in assessing prolapse treatment outcomes. We collected accelerometer data, which allowed us to assess patients' objective levels of activity postoperatively. Additionally, we collected data on multiple objective measures of physical function and activity, as well as occupation-related data that can be applied for evidence-based patient counseling for patients with similar occupational characteristics.

Our study also has several limitations. We chose a 3-month outcome because we hypothesized that any biologically plausible consequence of increased physical activity would likely manifest by 3 months after surgery. It is possible that a longer follow-up period would have led us to detect more occurrences of surgical failure. We are thus in the process of performing a follow-up study of 2-year symptomatic outcomes. We chose a 1-cm noninferiority threshold for our anatomic end point based on clinical relevance. While smaller margins could be considered, the more relevant outcome for prolapse is the symptomatic outcome, and thus, equal weight was placed on a coprimary symptomatic outcome rather than emphasizing increasingly narrow anatomic margins of questionable patient-important significance. Of note, point estimates of SLmax favored the expedited group, and we would still have demonstrated noninferiority had we chosen a margin of 0.5 cm, the smallest discernable difference in POPQ measurement.[24] Patients were not masked to treatment allocation preoperatively, which may have led to the observed imbalances in baseline preoperative accelerometer-based activity levels. We thus performed additional analyses controlling for baseline activity levels. Finally, accelerometers were used as a proxy to estimate mean IAP and have previously demonstrated good correlation with mean maximal IAP with a variety of activities. However, there are limitations to the information that the accelerometer may provide during static exercises that generate minimal accelerometer movement.[28]

Conclusion

In this randomized clinical trial, patients who received liberal activity instructions experienced noninferior anatomic and symptomatic outcomes at 3 months following vaginal or laparoscopic apical prolapse surgery with no major complications. Thus, while taking into account individual patient characteristics, it is reasonable to instruct patients undergoing minimally invasive prolapse surgery to resume physical activities ad lib, while reassuring patients that expedited resumption of physical activities will not result in worse outcomes.

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Acquisition, analysis, or interpretation of data: All authors.
Drafting of the manuscript: O'Shea.
Critical revision of the manuscript for important intellectual content: All authors.
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