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Preoperative Level II/III MRI measures predicting long-term prolapse recurrence after native tissue repair

Payton Schmidt, MD[1], **Luyun Chen, PhD**[1,2], **John O. DeLancey, MD**[1], **Carolyn W. Swenson, MD**[1]

[1]University of Michigan Department of Obstetrics and Gynecology

[2]University of Michigan Department of Biomedical Engineering

Abstract

Introduction and Hypothesis: To identify preoperative Level II/III MRI measures associated with long-term recurrence after native tissue prolapse repair.

Methods: Women who previously participated in pelvic floor research involving MRI prior to undergoing primary native tissue prolapse repair were recruited to return for repeat exam and MRI. Recurrence was defined by POP-Q (Ba/Bp>0 or C>−4); repeat surgery; or pessary use. Preoperative MR images were used to perform five Level II/III measurements including a new levator plate (LP) shape analysis at rest and maximal Valsalva. Principal component analysis (PCA) was used to evaluate LP shape variations. Principal component scores calculated for two independent shape variations were noted.

Results: Thirty-five women were included with a mean follow-up of 13.2 ± 3.3 years. Nineteen (54%) were in the success group. There were no statistical differences between success versus recurrence groups in demographic, clinical, or surgical characteristics. Women with recurrence had a larger preoperative resting levator hiatus (median 6.4 cm (IQR 5.7, 7.1) vs 5.8 cm (IQR 5.3, 6.3), p=.03). This measure was associated with increased odds of recurrence (OR 3.7, CI 1.1-12.2, p=.04). Using PCA, preoperative LP shape PC1 scores were different between success and recurrence groups (p=.02), with a more dorsally-oriented LP shape associated with recurrence.

Conclusions: Larger preoperative levator hiatus at rest and a more dorsally-oriented levator plate shape were associated with prolapse recurrence at long-term follow-up. For every 1 cm

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Corresponding Author: Payton Schmidt, 1500 E. Medical Center Dr., Ann Arbor, MI 48109, Phone: 217-390-2704, Fax: 734-647-9727, payton@med.umich.edu.

Author Contributions:
P Schmidt: data collection or management, data analysis, manuscript writing/editing
L Chen: protocol/project development, data collection or management, data analysis, manuscript writing/editing
JO DeLancey: protocol/project development, data collection or management, data analysis, manuscript writing/editing
CW Swenson: protocol/project development, data collection or management, data analysis, manuscript writing/editing

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increase in preoperative resting levator hiatus, the odds of long-term prolapse recurrence increases 3.7-fold.

Brief Summary:

Larger preoperative levator hiatus at rest and a more dorsally-oriented levator plate shape are associated with long-term recurrence after native tissue prolapse surgery.

Keywords

prolapse recurrence; prolapse surgery; surgical outcomes; hiatus; MRI

Introduction:

Over 200,000 women per year in the United States undergo surgery for pelvic organ prolapse (POP) [1,2]. Improvements in surgical management of the apex have led to better long-term outcomes for Level I support, so this is now rarely the site of surgical failure [3–5]. However, recurrence rates are still unacceptably high, with reoperation rates as high as 30% [6–8]. Recent evidence suggests that preoperative Level III factors, such as levator avulsion and enlarged genital and levator hiatus areas, may be important predictors of surgical failure when assessing women for prolapse <10 years after surgery [9–12]. However, a long-term (>10 years) comprehensive structural analysis of the association between prolapse recurrence and the status of Level III structural support factors before surgery is lacking. Additionally, more comprehensive measures of Level II/III support, such as levator plate shape, are needed to better understand the underlying structural mechanism of prolapse and its recurrence. Identifying structural factors that place women at high risk for prolapse recurrence prior to surgery could lead to novel surgical and non-surgical interventions that will improve outcomes and reduce recurrence risk.

At our institution, we have a unique cohort of women who underwent NIH-sponsored MR imaging for biomechanistic pelvic floor research studies and who subsequently had primary native tissue prolapse repair 8-18 years ago [13]. We recently developed an MRI-based strategy to comprehensively assess Level II/III structural support measures including: urogenital hiatus (UGH), perineal body location (PBL), levator hiatus (LH), levator area (LA), and levator plate (LP) shape. The primary objective of this study was to determine the association between *preoperative* Level II/III MRI measures and long-term recurrence after native tissue prolapse surgery.

Materials and Methods:

We performed a long-term follow-up cohort study of women who underwent primary vaginal reconstructive native tissue prolapse surgery by board-certified Female Pelvic Medicine/Reconstructive Surgery specialists at a single tertiary institution between January 2001 and August 2011. The study was approved by the University of Michigan institutional review board (HUM00150149). Women were included if they had previously been enrolled in prior pelvic floor research studies that included preoperative MRI of the pelvis (NIH P50 HD044406, NIH R01 HD035665). Methodology and recruitment for these studies has previously been published [13]. In brief, these studies recruited women with prolapse at or beyond the hymen (Pelvic Organ Prolapse Quantification system (POP-Q) [14] points Ba or Bp ≥0).

As part of the original research studies, women underwent an MRI of the pelvis and physical examination using the POP-Q system. Participants had previously consented to be re-contacted for future studies. Women were re-contacted, first by mail and then by a follow-up phone call, to inquire about interest, and those who met inclusion criteria and agreed to participate in the follow-up study returned for an office POP-Q examination and 3D stress MRI. For this study, only the preoperative MRIs were analyzed. Results of the long-term postoperative MRI findings and pelvic floor symptoms are presented in the companion manuscript titled "Long-Term Structural Failure Analysis After Native Tissue Prolapse Surgery: A 3D Stress MRI-Based Study." Demographic and clinical POP-Q data from the original study were previously collected and additional chart review was performed to abstract surgical data. Maximal preoperative prolapse size was defined as the largest (highest numerical value) POP-Q point between Ba, Bp, or C. Women were categorized as "success" versus "recurrence." Recurrence was defined by POP-Q measures (Ba>0, Bp>0, or C>−5)—criteria chosen to reflect the POP-Q values >90th percentile in the population from which we recruited, based on a prior study [15]—and/or retreatment with either surgery or pessary.

MRI protocol

The MRI protocols used to obtain preoperative static and straining MRI images have been previously published [16]. All subjects had resting MRI of the pelvic floor in the axial, sagittal, and coronal planes, and some, but not all, participants had midsagittal straining images and 3D stress MR imaging. To briefly summarize, for the midsagittal 2D straining sequences, patients were instructed to perform a maneuver where they were instructed to relax their pelvic floor and then strain with increased effort over the span of approximately 20 seconds to obtain a graded straining response [17]. In the 3D stress MRI sequences, women were instructed to perform and hold a maximal straining maneuver for approximately 20 seconds to obtain 3D images of the pelvis with the prolapse protruding maximally [16]. These maneuvers were repeated as necessary to produce a prolapse consistent with that seen during physical examination.

Level II/III MRI measurements

Levels of support, which can be visualized on MRI [18], were assessed as follows: MRI measurements were performed in the mid-sagittal plane at rest and maximal Valsalva (see Figure 1). Preoperative straining images were available for 23 participants, 11 in the success group and 12 in the recurrence group, as 2D and 3D straining MRI techniques had not been routinely implemented in the earliest studies. The mid-sagittal image to be used for measurements was chosen by identifying the slice that had the most hypo-intense pubic bone—which is consistent with the pubic symphysis—and clear delineation of the sacrum, coccyx, and sacrococcygeal joint. Two reference lines were utilized for measurements—the sacrococcygeal to inferior pubic point (SCIPP) line and the Pelvic Inclination Correction System (PICS) line, which is a horizontal reference line 34 degrees caudal to the SCIPP line

[19]. The SCIPP line measures were compared between a patient's original MRI and her long-term follow-up study MRI to ensure consistency in measurements.

Using ImageJ software [20], the following points were marked (see Figure 1): 1) inferior pubic point of the pubic symphysis; 2) perineal body; 3) most superior point of the external anal sphincter; 5) middle of the pubrectalis bundle that was approximately the shortest distance from the pubic symphysis to the levator plate; 9) inferior coccyx; and 10) sacrococcygeal joint. The remaining points were equal sampling points (4,6,7,8), which were marked at approximately half the distance between the above-mentioned anatomic landmarks, in numeric order, to allow for more accurate curvature measurements. The levator plate was defined as the curved line extending from point (3) to (10). Other measurements included: urogenital hiatus (UGH)—length between the inferior pubic point to the perineal body; levator area (LA)—bounded by the pubic symphysis, perineal body, levator plate, and SCIPP line; levator hiatus (LH)—length between the pubic symphysis and the middle of the puborectalis muscle bundle; and perineal body location (PBL)—vertical distance from the PICS line to the perineal body. Resting measurements are denoted with a subscript "R" and straining images are denoted with a subscript "S" (*i.e.*, UGH_R=resting UGH and UGH_s=straining UGH).

Levator ani muscle avulsion was graded by one of the senior investigators based on a previously published method [21]. For this analysis, the patient was considered to have a levator avulsion if a 'major defect' was seen on MRI, which is defined as either 100% of muscle missing on at least one side or >50% of the muscle missing on both sides.

Levator plate shape analysis

The levator plate is a curved structure and the previously published levator plate angle evaluation only captures one aspect of this phenomenon [17]. Therefore, to do a more comprehensive analysis of the LP, we performed statistical shape analysis using a PCA technique in a custom Python program. First, LP shape geometry was scaled proportionately to achieve a standard size based on a SCIPP line length of 10 cm. Then, the plotted LP points (points 3-10, Figure 1) were aligned by importing the 3D coordinates of all the identified points into the custom Python-based software for post-processing and the measurements of three subsystems were calculated. The coordinates of all points were transformed from the scanner coordinates system to a standardized 3D PICS [22]. Next, the mean LP shape was calculated for women with and without long-term recurrence at both rest and strain. Two separate PCAs were performed after aligning and normalizing the LP landmarks for rest and strain. A covariance matrix representing variation of the LP shape from the overall mean shape was constructed. Principal components (PCs) represent the directions (eigenvectors) of shape variations that are statistically independent [23]. Two PCs (PC1 and PC2) representing the most significant independent shape variations were identified and reported. For each subject, PC1 and PC2 scores were then calculated by projecting subject-specific LP shape coordinate data onto the PC1 and PC2 eigenvectors. PC1 and PC2 scores were then compared between women with long-term success and recurrence.

Normal controls

To establish the ‘normal range’ for each Level II/III parameter, measurements were performed in MRIs from 30 normal controls without prolapse (POP-Q Ba or Bp points$\leq$ 0 cm or C ≤ -4) from prior studies [24]. Measurements were made as described above.

Statistical analysis

Bivariate analyses were used to compare women with surgical success versus recurrence. Demographic, clinical, POP-Q, MRI, and PCA measurements were compared using student t-tests, Mann-Whitney U, Chi-squared, or Fischer’s exact tests where indicated. Tests of normality and evaluation of skewness and kurtosis was performed for each variable. Parametric data was reported as mean with standard deviation (SD). If the data was not normally distributed or skewed, it was considered non-parametric and reported as median with interquartile range (IQR). MRI measures and PCA scores were then compared between each prolapse group (success and recurrence). “Failure frequency” was defined as the proportion of women outside of the range (5^{th}-95^{th} percentile) of normal controls and was calculated for each prolapse group and compared using Mann-Whitney U tests. Binary logistic regression analysis was performed and included variables that were thought to be clinically significant or found to be significant in the bivariate analysis. Spearman’s rho correlation coefficients (r_s) were calculated for PC1 and MRI measures. Statistical analysis was performed using SPSS (version 26; IBM, Armonk, NY, USA) software.

Results

A total of 35 women were included in the study—19 (54%) in the success group and 16 (45%) in the recurrence group. Of the women with recurrence, 13 (81%) had an anatomic recurrence only, two (13%) had another prolapse surgery, and one (6%) had both repeat surgery and an anatomic recurrence at long-term follow-up. None of the participants used a pessary after their initial surgery. Mean age at the long-term follow-up study visit was 67.7 ± 8.9 years, with a mean follow-up time of 13.2 ± 3.3 years (total range 8-18 years) from primary surgery. No statistically significant differences were seen between groups with regard to age, BMI, parity, surgical procedures performed, or preoperative POP-Q measurements (Table 1). Prolapse groups and controls were similar in terms of age, BMI, and parity; however, as expected, POP-Q measures differed significantly (Appendix).

Level II/III MRI measurements

Figures 2 and 3 show the comparison of resting and straining preoperative MRI measurements and corresponding failure frequencies between women with success and recurrence. Compared to the success group, women with recurrence had a 12% larger resting LH_R and a 6x greater LH_R failure frequency rate. There was a trend toward larger $UGH_R$and larger LA_R measures in the recurrence group; however, these differences did not reach statistical significance. PB_R was similar between groups and almost all women were within the normal range. After controlling for age at surgery, preoperative BMI, parity, if an apical suspension was performed, and maximal preoperative prolapse size, logistic regression showed that for every 1 cm increase in preoperative LH_R size, the odds of prolapse recurrence increased 8-fold (OR 8.2, CI 1.4-48.9, p=.02).

Straining MRIs were available for analysis in 11 (58%) in the success group and 12 (75%) in the recurrence group. No statistically significant differences were seen in straining MRI measurements or failure frequency of measurements between groups. Using LA_S measures, a post-hoc power analysis using 80% power and alpha=.5 was performed; based on this, 708 women in each group would be needed to be able to detect significant differences in straining measures.

PCA analysis of LP shape

Each PCA shape analysis identified two main modes of shape variations (PC1 and PC2). At rest, PC1 accounted for 61% of shape variation and PC2 accounted for an additional 30% of variation (Figure 4). The PC1 scores differed significantly between success and recurrence groups (p=.03), while PC2 score distributions were similar between groups. PC1 scores were strongly correlated with UGH_R (r_s=.72, p<.001); LH_R (r_s=.83, p<.001); and LA_R (r_s=.72, p<.001).

Five (30%) women in the recurrence group had a PC1 score outside the range of the success group, with a more dorsally-oriented shape. When compared to rest of the cohort (n=30) whose LP PC1 shapes were within the range of the success group, these five women with extreme resting LP PC1 shapes also significantly differed in terms of the other Level III measurements: a 34% larger UGH_R (5.5 cm [5.3, 5.8] vs 4.1 cm [3.5, 4.7] cm, p=.004); 5% larger LH_R (33.8 cm^2 [32.7, 33.9] vs 32.1 cm^2 [27.2, 39.8], p=.003); and 5% larger LA_R (29.4 cm^2 [28.1, 30.7] vs 21.0 cm^2 [17.4, 26.4], p=.02).

For straining LP shape, two significant modes were also identified and accounted for 53% (PC1) and 40% (PC2) of shape variation (Figure 5). However, PC1 and PC2 for straining LP were not significantly different between success and recurrence groups.

Discussion

In this long-term follow-up study of women who underwent native tissue prolapse surgery at an average follow-up of 13 years, two preoperative resting MRI parameters—LH_R size and LP shape—were found to be associated with prolapse recurrence, while no demographic or clinical factors were. A strong correlation between LH_R and PC1 scores was found—suggesting a shared mechanism for prolapse and its recurrence.

Existing studies identifying Level III factors associated with prolapse recurrence have focused on straining measurements, such as an enlarged preoperative [12,25,26] and postoperative genital hiatus size on POP-Q [12,25,27] and levator hiatus size on ultrasound [9,28,29]. Our study is unique in that we assessed MRI measures made before surgery at both rest and strain. In doing so, we found that resting measures were more strongly associated with long-term prolapse recurrence. One explanation for this is that with prolapse, straining measures may simply reflect prolapse size, but resting measures may more accurately reflect the baseline status of pelvic floor support and may therefore be more indicative of structural impairments. Furthermore, straining measures are subject to several confounding factors that do not affect resting measures, including prolapse size, straining effort, and the participant's ability to voluntarily control and coordinate pelvic muscle relaxation during Valsalva maneuvers. These confounding factors are reflected in the wide variation of "normal ranges" seen with straining measures but not resting measures (Figures 2 & 3, blue-shaded boxes).

Our study also adds to the existing literature by assessing preoperative clinical and MRI Level II/III measures. Identifying preoperative structural factors associated with prolapse recurrence is important for determining possible failure mechanisms and identifying preoperative structural targets. A focus of recent clinical research has been on reducing prolapse recurrence by surgical reduction of an enlarged genital hiatus. Two studies have shown that women with a preoperative POP-Q GH of >4 cm, that remained persistently enlarged at >4 cm postoperatively after native tissue prolapse repair [12] and robotic sacrocolpopexy [25], had a 4.4-fold and 5.3-fold increased odds of prolapse recurrence, respectively. However, clinical measures of GH are made at maximal strain and again may be enlarged because prolapse is dilating an otherwise normal hiatus. Furthermore, these studies were limited to ≤12-month follow-up, so may not be reflective of longer term outcomes. In contrast to those studies, we did not find that preoperative measures of genital hiatus, either at rest or strain, on POP-Q or MRI were significantly associated with long-term recurrence.

In the current study, the preoperative parameter that was significantly larger among women with recurrence was LH_R, with every 1 cm increase associated with a 3.7-fold increased odds of recurrence. Likewise, failure frequency for LH_R was 6x greater in the recurrence group compared to those with success. Our results support findings of prior research highlighting the importance of measures of levator status in prolapse recurrence. Two separate studies found that every 1 cm^2 increase in preoperative straining levator area on translabial ultrasound was associated with a 7% (Rodrigo et al) and 8% (Vergeldt et al) increased odds of recurrence [28,29]. In a retrospective study of 66 women who underwent preoperative 3D MRI prior to laparoscopic uterosacral ligament suspension, Wyman et al. reported that women with surgical failure had increased resting levator ani subtended volumes—a measure of deepening of the levator bowl [30].

We also identified that women with prolapse recurrence had a distinctly more dorsally-oriented LP shape. This shape variation is consistent with prior studies, as levator ani descent leads to an increased levator area [9,28,29] and a more caudally-oriented LP angle. However, our study extends the existing literature by using PCA, a relatively novel approach to measuring pelvic floor changes, which allowed us to perform a more complete analysis of the LP by quantifying shape changes along the entire length, as opposed to measuring only one aspect like LP angle [17]. In doing so, we identified five women in the recurrence group with an LP shape out of the range of the success group. It is possible that for this subgroup of women, impaired support of the LP may have predisposed them to surgical failure. Future studies focused on LP shape changes with prolapse and prolapse recurrence are needed to determine the cause of dorsal displacement of the LP and whether this could be a target of novel therapies.

In contrast to prior studies, findings from the current study may offer some insight into structural causes of prolapse recurrence. LH_R and LP shape were strongly correlated—

suggesting that both measurements reflect the same phenomenon, which is sagging and posterior ballooning of the levator ani. The prevalence of levator ani avulsion was nearly identical in both groups—suggesting that while this injury may increase the risk of developing prolapse, it is not a major player in prolapse recurrence. Furthermore, the portion of the levator ani where the biggest group differences in LH_R and LP shape are seen is not the pubococcygeus portion, where childbirth-related LA avulsion occurs [24], but rather more cephalad in the puborectalis and ilicoccyegeus portions of the levator ani. Changes in the this region of the levator ani muscle complex have also been significantly associated with pelvic floor aging [31] and prolapse [32], suggesting focus on this area should be prioritized in future research. Together, these findings suggest that preoperative levator impairment resulting in a generalized descent and ballooning of the levators is a potential mechanism for prolapse recurrence. Current standard surgical techniques for prolapse repair do not directly address levator impairments or resting levator hiatus size [33]; therefore, these structural impairments likely remain unaddressed with surgery, which may explain their association with recurrence.

The strengths of our study are that we had long-term (average follow-up time >13 years), comprehensive preoperative POP-Q and MRI resting and straining data on women who underwent native tissue prolapse repair. Additionally, we also compared MRI measurements with their respective normal ranges, as defined in 30 women with normal pelvic floor support. Limitations include our small sample size, which could lead to bias; therefore, larger studies are needed to verify our results. Additionally, our study design could have led to participation bias, as women who thought there might be something wrong may have been more likely to want further evaluation.

In this long-term follow-up study, we found that preoperative resting measures of an enlarged LH and a more dorsally-oriented LP shape are associated with long-term prolapse recurrence. Preoperative POP-Q measures were not associated with recurrence—suggesting that our current system of clinical evaluation is incomplete in assessing Level II and Level III parameters. Measuring preoperative LH and LP shape may be important to identify those at high risk of recurrence. Future studies are needed to confirm our findings and determine the impairment mechanism, as well as to investigate the feasibility of these parameters as targets for novel diagnostic and therapeutic interventions.

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Appendix.: Long-term follow up demographics and POP-Q measures in success versus recurrence groups

Characteristic	Success (n=19)	Recurrence (n=16)	P-value
Demographics			
Age at follow-up, years	66 ± 8.1	68 ± 10.0	.59
BMI, kg/m^2	27 ± 4.8	27 ± 2.6	.42
Parity	2.0 (2.0, 3.0)	2.0 (2.0, 4.0)	.12
Long-term Follow-up POP-Q, cm			
Max prolapse size	0.0 (−1.0, 0.0)	1.0 (0.5, 1.5)	<.001
Ba	−1.0 (−2.0, 0.0)	1.0 (0.0, 1.0)	<.001
Bp	−1.0 (−2.0, 0.0)	−1.0 (−2.0, 0.0)	.31
C	−7.0 (−8.0, −6.0)	−6.0 (−6.5, −3.5)	.015
GH rest	2.0 (1.5, 2.5)	3.0 (2.5, 3.5)	.006
GH strain	2.5 (2.0, 3.5)	3.5 (3.0, 4.5)	.07

Data presented as mean ± SD, or median (interquartile range)

POP-Q=Pelvic Organ Prolapse Quantification; GH=genital hiatus

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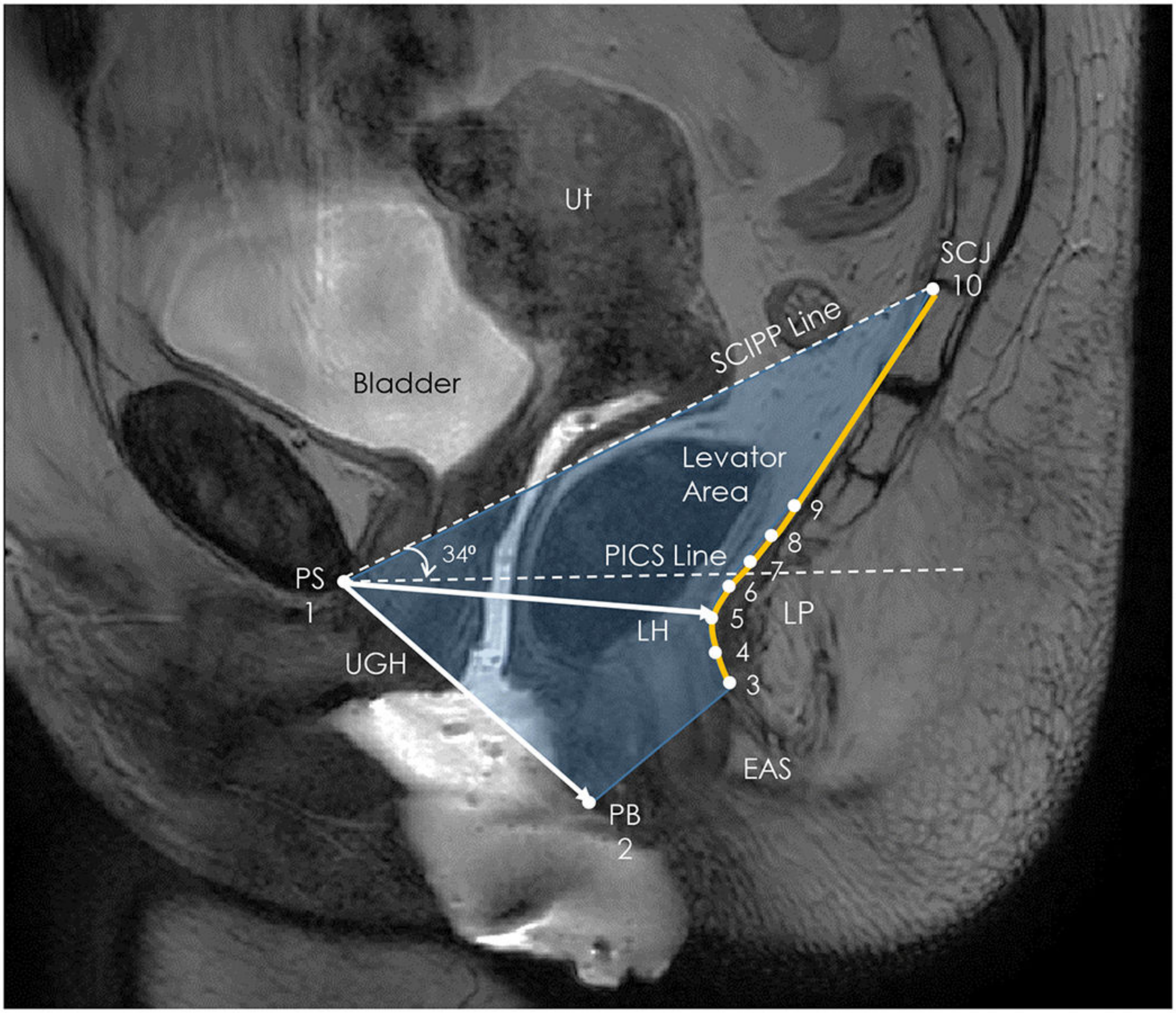

Figure 1. Mid-sagittal MRI measurements

PS: pubic symphysis; UGH: urogenital hiatus; PB: perineal body; EAS: external anal sphincter; LP: levator plate; LH: levator hiatus; SCJ: sacrococcygeal joint; SCIPP line: sacrococcygeal to inferior pubic point line; Ut: Uterus; PICS line: horizontal reference line. Eleven anatomical points were marked, with points 3-9 placed equidistant along the levator plate from the top of the EAS to the bottom of the coccyx.

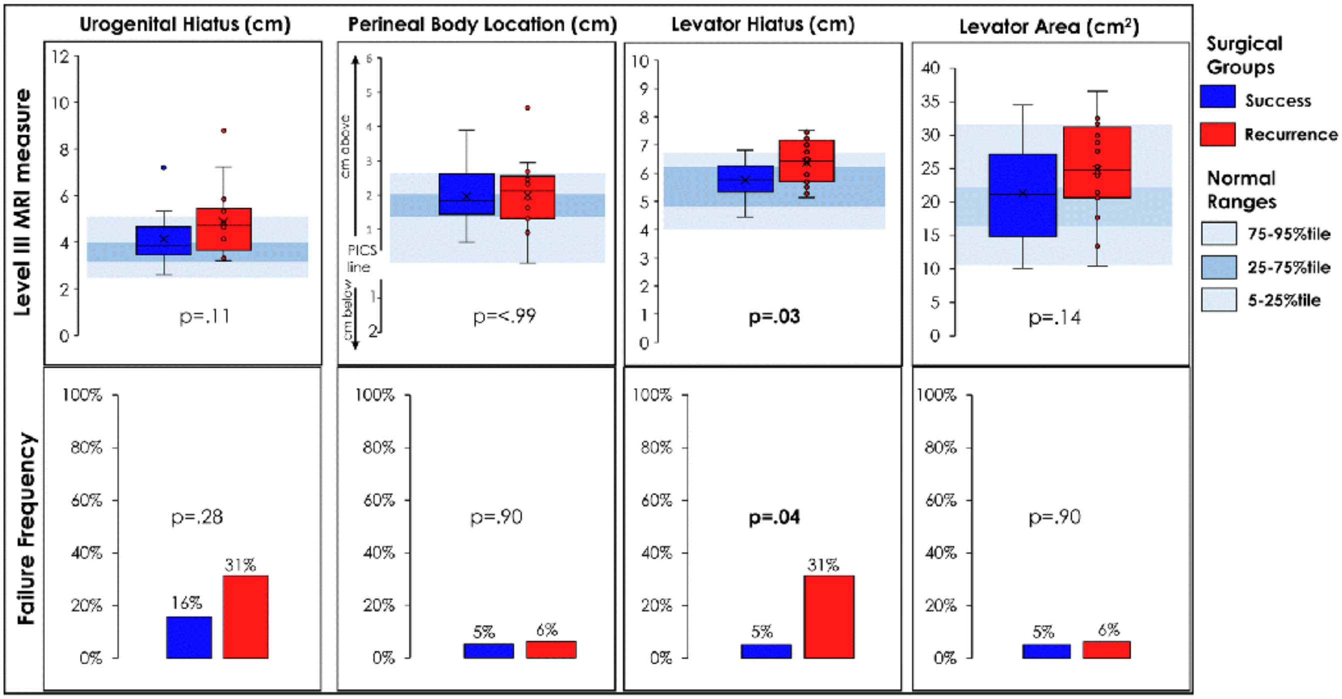

Figure 2. Resting preoperative MRI measurements compared to normal range in women with long-term success versus recurrence

The bottom error bar indicates the minimum value to the 25th percentile and the top error bar indicates the 75th percentile to the maximum value.

*Failure frequency is defined as the proportion of women whose MRI measurement is outside the normal range.

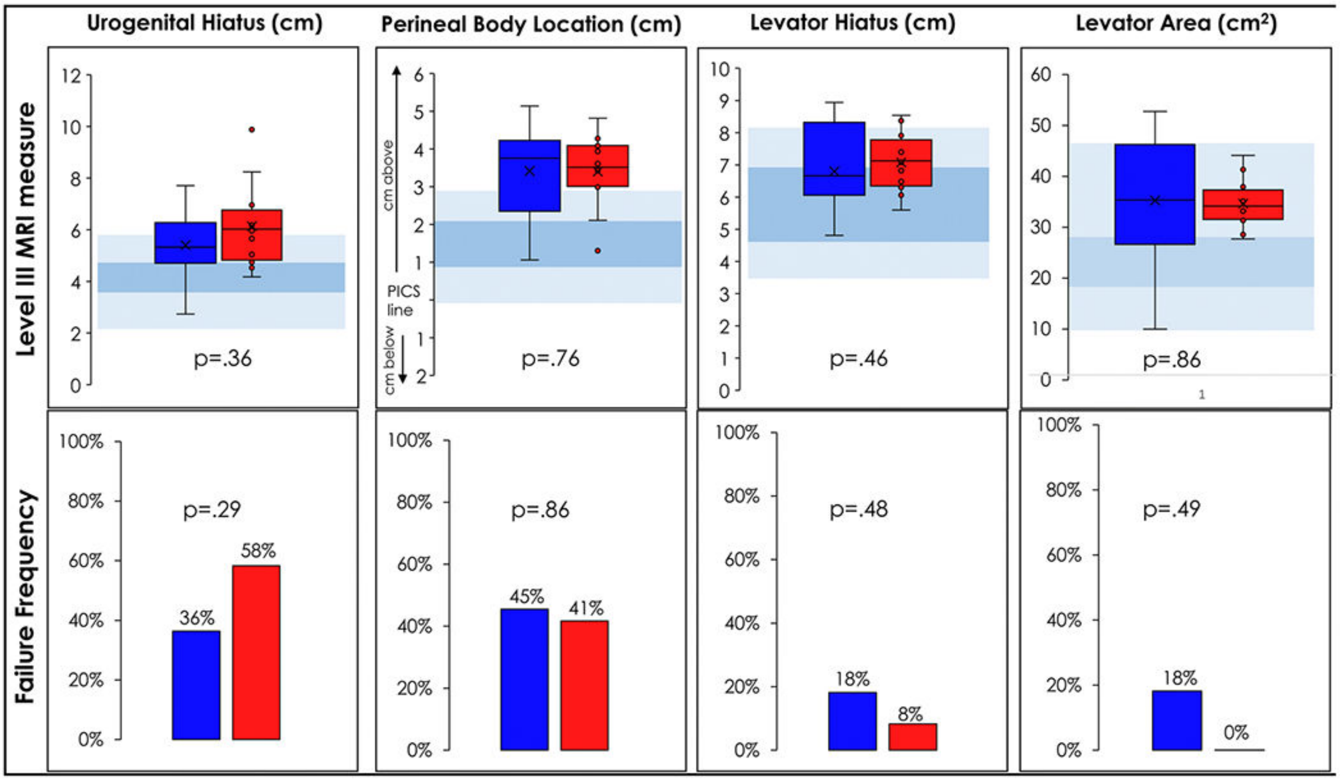

Figure 3. Resting preoperative MRI measurements compared to normal range in women with long-term success versus recurrence

The bottom error bar indicates the minimum value to the 25th percentile and the top error bar indicates the 75th percentile to the maximum value.

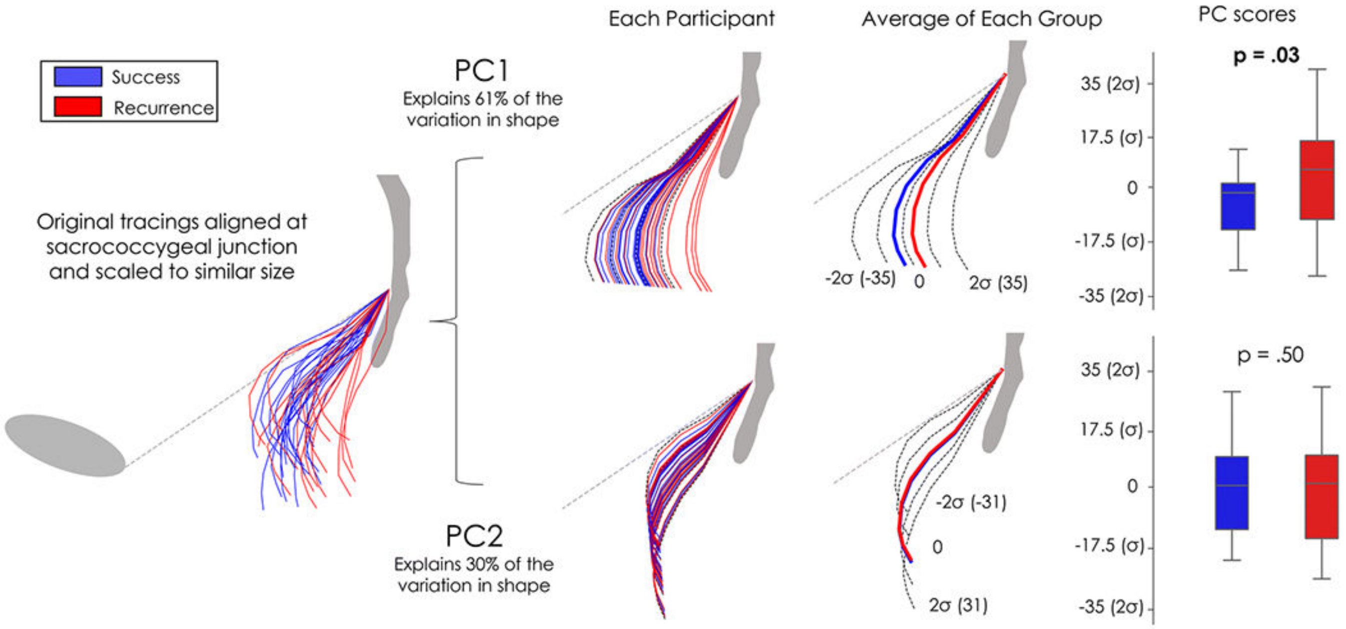

Figure 4. Straining levator plate shape analysis comparing women with long-term success and recurrence

The bottom error bar indicates the minimum value to the 25th percentile and the top error bar indicates the 75th percentile to the maximum value.

PC=principal component

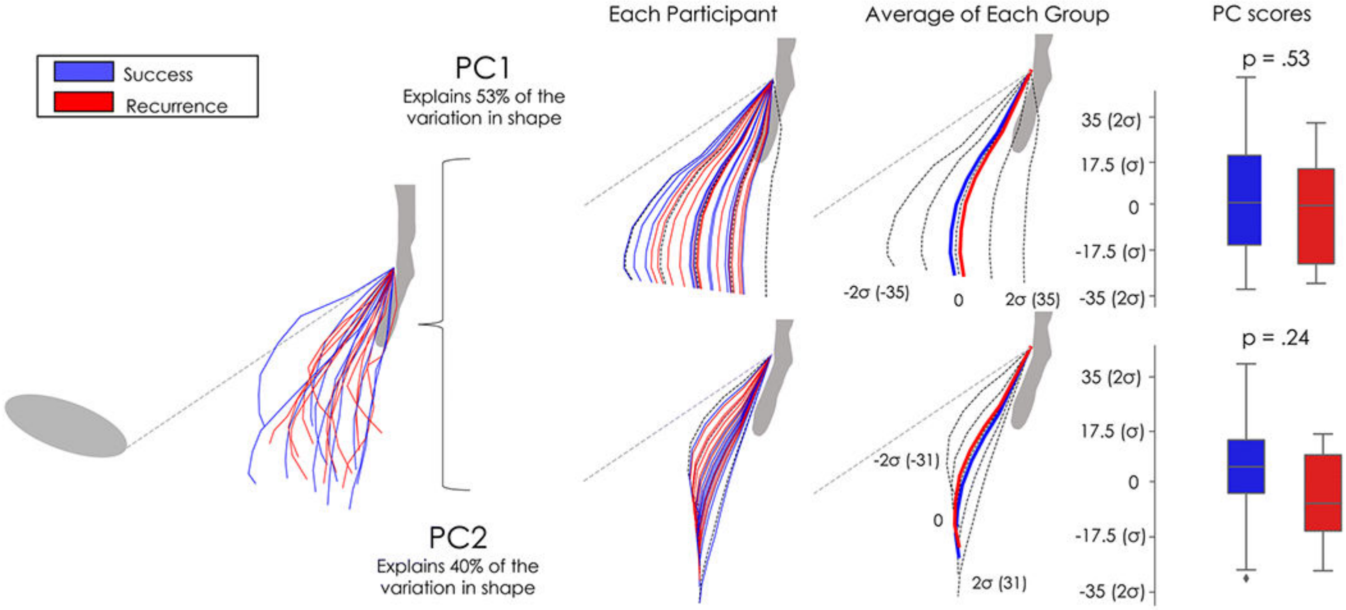

Figure 5. Straining levator plate shape analysis comparing women with long-term success and recurrence

The bottom error bar indicates the minimum value to the 25th percentile and the top error bar indicates the 75th percentile to the maximum value.

PC=principal component

Table 1.

Preoperative demographics, prolapse procedures performed, and preoperative POP-Q measures in success versus recurrence groups

Characteristic	Success (n=19)	Recurrence (n=16)	P-value
Demographics			
Age at surgery, years	53.6 ± 8.7	55.6 ± 9.3	.47
BMI, kg/m^2	26.1 ± 3.4	26.2 ± 3.5	.78
Parity	2.0 (2.0, 3.0)	2.0 (2.0, 4.0)	.88
Follow-up time, years	13.2 ± 3.3	12.0 ± 2.5	.19
Procedures performed during native tissue prolapse surgery			
Hysterectomy	11 (58)	9 (56)	.92
Apical suspension	10 (53)	12 (75)	.51
Sacrospinous ligament suspension	4 (21)	6 (38)	.28
Uterosacral ligament suspension	0 (0)	2 (13)	.20
Other intraperitoneal colpopexy[a]	7 (37)	6 (38)	.96
Anterior repair	16 (84)	12 (75)	.95
Posterior repair	13 (68)	13 (81)	.46
Incontinence procedure[b]	7 (37)	5 (31)	.72
Preoperative POP-Q, cm			
Max prolapse size	2.0 (1.0, 5.0)	3.0 (2.0, 4.0)	.28
Ba	1.0 (−0.5, 3.5)	3.0 (0.5, 4.0)	.57
Bp	−1.0 (−2.0, 1.0)	0 (−2.0, 2.0)	.13
C	−3.0 (−5.5, 1.0)	−3.0 (−4.5, −3.0)	.92
GH rest	5.0 (3.5, 6.0)	5.0 (4.0, 6.0)	.62
GH strain	5.5 (4.5, 7.0)	6.0 (5.0, 7.0)	.37
Levator avulsion	7 (42)	7 (44)	.92

Data presented as mean ± SD, n (%), or median (interquartile range)

[a] McCall’s culdoplasty, Richardson-angle suture

[b] Incontinence procedures include: retropubic midurethral sling, autologous pubovaginal sling POP-Q=Pelvic Organ Prolapse Quantification; GH=genital hiatus