UROGYNECOLOGY

The Pelvic Floor Complication Scale: a new instrument for reconstructive pelvic surgery

Robert E. Gutman, MD; Ingrid E. Nygaard, MD; Wen Ye, PhD; David D. Rahn, MD; Matthew D. Barber, MD, MHS; Halina M. Zyczynski, MD; Leslie Rickey, MD; Charles W. Nager, MD; R. Edward Varner, MD; Kimberly Kenton, MD, MS; Kimberly J. Dandreo, MSc; Holly E. Richter, PhD, MD; for the Pelvic Floor Disorders Network and the Urinary Incontinence Treatment Network

OBJECTIVE: The purpose of this study was to develop and test a unique, new pelvic floor surgery complication scale and compare it with an existing validated measure.

STUDY DESIGN: Surgeons from 2 clinical trials networks rated complications based on perceived patient bother, severity, and duration of disability to develop a Pelvic Floor Complication Scale (PFCS). PFCS scores were calculated for subjects in 2 multicenter pelvic floor surgical trials. The PFCS and modified Clavien-Dindo scores were evaluated for associations with length of hospitalization, satisfaction, and quality-of-life measures (Health Utilities Index, Short Form-36, Urogenital Distress Inventory, and Incontinence Impact Questionnaire).

RESULTS: We calculated PFCS scores for 977 subjects. Higher PFCS and Clavien-Dindo scores similarly were associated with longer length of hospitalization ($P < .01$), lower satisfaction ($P < .01$), lower Health Utilities Index scores ($P = .02$), lower Short Form-36 scores ($P = .02$), higher Urogenital Distress Inventory scores ($P < .01$), and Incontinence Impact Questionnaire scores ($P < .01$) at 3 months. No associations were present at 1 year.

CONCLUSION: The PFCS compares favorably to the validated modified Clavien-Dindo instrument.

Key words: Clavien-Dindo scale, complication, quality-of-life measure, reconstructive pelvic surgery, surgical outcome

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Pelvic floor disorders, like pelvic organ prolapse and urinary incontinence, often impair a woman's quality of life (QoL) but rarely, in themselves, result in significant morbidity or death. The surgical procedures that are used to correct these conditions impart some risk of morbidity.[1] Given this, patients and physicians must weigh carefully the benefits and risks of various treatment options when considering surgery. Successful surgical outcomes should take into account perioperative and postoperative morbidity. For example, a surgery that has excellent anatomic and symptomatic improvement, but increased morbidity, may not be as desirable as a surgery that has good anatomic

From the Department of Obstetrics and Gynecology, Washington Hospital Center, Georgetown University, Washington, DC (Dr Gutman); the Department of Obstetrics and Gynecology, University of Utah School of Medicine, Salt Lake City, UT (Dr Nygaard); the Department of Biostatistics, University of Michigan Medical School, Ann Arbor, MI (Dr Ye); the Department of Obstetrics and Gynecology, University of Texas Southwestern Medical Center at Dallas, Dallas, TX (Dr Rahn); the Department of Obstetrics and Gynecology, Cleveland Clinic Foundation, Cleveland, OH (Dr Barber); the Department of Obstetrics and Gynecology, University of Pittsburgh School of Medicine, Pittsburgh, PA (Dr Zyczynski); the Department of Urology, University of Maryland School of Medicine, Baltimore, MD (Dr Rickey); the Department of Obstetrics and Gynecology, University of California, San Diego, School of Medicine, San Diego, CA (Dr Nager); the Department of Obstetrics and Gynecology, University of Alabama School of Medicine, Birmingham, AL (Drs Varner and Richter); the Departments of Obstetrics and Gynecology and Urology, Stritch School of Medicine, Loyola University, Chicago, IL (Dr Kenton); and the Department of Biostatistics, New England Research Institutes, Watertown, MA (Ms Dandreo).

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and symptomatic improvement with minimal morbidity. Unfortunately, our ability to compare the outcomes of different procedures or surgical approaches is hampered by a lack of uniform reporting of perioperative morbidity. Perioperative complications are generally reported in surgical studies; however, complications are often reported only as a summation or are divided into major and minor categories at the discretion of the author.

In recent years, clinical investigators published several surgical complication grading systems that allow more uniform classification and reporting of perioperative complications.[2-4] These systems broadly classify complications into 1 of several groups and are intended for use in all surgical disciplines. The Clavien-Dindo system classifies complications into 1 of 4 categories that are based on the type of therapy that is needed to correct the complication.[2] This system is reproducible, easy to apply, has been validated compared with complexity of surgery and length of hospital stay in general surgery populations, and has been used recently in several studies that have evaluated pelvic reconstructive procedures.[5-8] However, current systems are not condition specific and do not take into account the unique complications that are associated with pelvic reconstructive surgery. The objective of this study was to develop a peri- and postoperative complication scale that is specific to pelvic reconstructive surgery and to compare its ability to predict factors that are associated with perioperative morbidity with the Clavien-Dindo system.

Materials and Methods

Investigators from the Pelvic Floor Disorders Network and the Urinary Incontinence Treatment Network rated specific intraoperative plus immediate and delayed postoperative complications on a scale from 0-10 based on severity, patient bother, and duration of disability. Scoring was as follows: 0 = none, no bother, no clinical significance; 2 = minor, bother, no clinical significance, transient, self-limited; 4 = minor, bother, requires intervention; 6 = major, no risk or low risk, no long-term sequelae; 8 = major, moderate or high risk, long-term sequelae; and 10 = major, life threatening, permanent disability. We then created the Pelvic Floor Complication Scale (PFCS) using the information that we had obtained (Table 1).

PFCS scores were calculated retrospectively during the first postoperative year for participants in 2 randomized pelvic floor surgical trials: colpopexy and urinary reduction efforts (CARE), which compared abdominal sacrocolpopexy with or without Burch colposuspension in stress continent women[6] and the stress incontinence surgical treatment efficacy trial (SISTEr), which compared Burch colposuspension and fascial sling in women with stress incontinence.[7] This analysis was exempt from Institutional Review Board review. We excluded women with no 3-month follow-up data. Complications for each study had been evaluated already, adjudicated, and transferred into a database. Information from these databases was extracted to help identify the complication onset, resolution, severity, and treatment. Definitions were created for each complication to use as a guide for cases in which the information from the database was insufficient to categorize the complication (Table 1). For example, clear, mutually exclusive definitions were constructed to distinguish wound infections with separation (suprafascial dehiscence) from seroma, hematoma, or cellulitis (without dehiscence and/or resolved with antibiotics). When a reoperation or readmission was required for a complication, the highest single PFCS score that was related to the complication was selected.

Two independent investigators reviewed all complications that occurred during the first year after surgery in each study and assigned a time period and PFCS score. A third investigator adjudicated any discrepancies that occurred. There were 3 time periods: perioperative (operating room to discharge), 3 postoperative months (discharge to 90 days), and 1 postoperative year (91-365 days). Complications that were being actively managed over >1 time period generated a separate complication score for each time period. An example of this includes a vaginal mesh exposure that was trimmed in the office at 2 months and in the operating room at 6 months after the surgery. Individual complication scores for each time period were summed. We defined the PFCS composite score as the sum of all complications that occurred during the perioperative and 3-month postoperative time periods. Medical complications that were >6 weeks after surgery and were not believed by 3 reviewers to be related to the original surgery did not receive a PFCS score.

Patient demographics that were collected included age, race, marital status, education, tobacco use, menopause status, previous pelvic surgery, diabetes mellitus, body mass index, and preoperative pelvic organ prolapse quantification examination stage. QoL measures that included the Health Utilities Index (HUI) for SISTEr, Short Form-36 Health Survey (SF-36) for CARE, and Urogenital Distress Inventory (UDI) and Incontinence Impact Questionnaire (IIQ) for both studies were available at baseline, 3 months, and 1 year. HUI ranged from 0-1; higher value indicate better health, but scores can also be negative (lowest possible value, −0.36), which reflects health states that are considered worse than death. The mental and physical component summary scores of the SF-36 range from 0–100 (higher scores indicate better health). UDI scores range from 0–300, and IIQ scores range from 0–400 (higher scores indicate worse QoL). Satisfaction was measured by a global satisfaction question with a 5-point Likert scale from "very dissatisfied" to "very satisfied" at 3 months and 1 year. Additionally, surgical information that included the route of surgery, type of anesthesia, length of surgery, and postoperative length of hospitalization (LOH) was obtained.

Complications were also assessed with a modified Clavien-Dindo scale.[2] The original Clavien-Dindo scale was validated for immediate postoperative complications before discharge in a general surgical population. The scale ranges from grade I-IV; higher scores indicate

TABLE 1
Pelvic Floor Complication Scale: peri- and postoperative morbidity with physician-rated complication severity levels

Morbidity	Mean	SD
Intraoperative (before leaving operating room)		
OR1: Bowel injury with colostomy	8.2	0.7
OR2: Bowel injury with resection and primary repair	6.9	1.0
OR3: Bowel injury with primary repair (does not include serotomy)	5.9	1.4
OR4: Vascular injury that requires vascular surgeon	7.7	1.3
OR5: Ureteral injury that requires reanastomosis	7.0	0.9
OR6: Ureteral injury that requires stent	5.8	1.3
OR7: Ureteral injury that is resolved with removal of suture	4.4	1.6
OR8: Aspiration pneumonia	6.6	1.3
OR9: Transfusion	5.2	1.4
OR10: Estimated blood loss >1000 mL	5.3	1.7
OR11: Urethral injury	5.8	1.3
OR12: Cystotomy that requires repair	4.7	1.2
OR13: Cystotomy that does not require repair	3.1	1.2
Immediately postoperation (after leaving operating room to discharge)		
IP1: Thromboembolic event (deep venous thrombosis/pulmonary embolism)	8.0	1.4
IP2: Small bowel obstruction	7.0	1.2
IP3: Ileus (reversal in diet advance)	3.8	1.2
IP4: Persistent nausea/vomiting >24 hours (cause uncertain)	3.6	1.3
IP5: Postoperative fever that requires antibiotics (cause uncertain)	3.5	1.1
IP6: Postoperative fever that resolves without antibiotics	2.3	1.2
IP7: Myocardial infarction/congestive heart failure	8.6	1.0
IP8: Wound infection with fascial dehiscence	7.2	1.3
IP9: Wound infection/separation with suprafascial dehiscence	5.0	1.2
IP10: Wound infection/seroma/hematoma with no dehiscence (cellulitis resolved with antibiotics)	4.0	0.9
IP11: Fistula	7.5	1.3
IP12: Neuropathy that is persistent at time of discharge	6.0	1.6
IP13: Neuropathy that resolves before discharge	3.1	1.4
IP14: Urinary tract infection (bacteriuria, pyuria, treated with antibiotics)	3.3	1.1
IP15: Bleeding: reoperation required	7.3	1.1
IP16: Bleeding: transfusion required	5.3	1.3
IP17: Bleeding: observation only	3.4	1.4
IP18: Reoperation because of an unrecognized bladder injury	6.9	0.9
IP19: Reoperation because of an unrecognized ureteral injury	7.6	0.9
IP20: Reoperation because of an unrecognized bowel injury	8.3	1.0
IP21: Reoperation because of any other complication of original surgery	7.2	0.9
IP22: Pneumonia	5.7	1.4
IP23: Pulmonary edema	5.9	1.5

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(continued)

TABLE 1
Pelvic Floor Complication Scale: peri- and postoperative morbidity with physician-rated complication severity levels *(continued)*

Morbidity	Mean	SD
IP24: Mental status changes	6.0	1.6
IP25: Pelvic abscess	6.6	1.5
IP26: Sepsis, disseminated intravascular coagulation	9.0	1.1
Delayed postoperative (after discharge)		
DP1: Thromboembolic event (deep venous thrombosis/pulmonary embolism)	8.2	1.4
DP2: Small bowel obstruction	7.1	1.0
DP3: Ileus (reversal in diet advance)	4.6	1.4
DP4: Persistent nausea/vomiting (cause uncertain)	4.3	1.5
DP5: Postoperative fever that requires antibiotics (cause uncertain)	4.1	1.1
DP6: Postoperative fever that resolves without antibiotics	2.7	1.2
DP7: Myocardial infarction/congestive heart failure	8.6	1.1
DP8: Wound infection with fascial dehiscence	7.5	1.2
DP9: Wound infection/separation with suprafascial dehiscence	5.3	1.3
DP10: Wound infection/seroma/hematoma - no dehiscence (cellulitis resolved with antibiotics)	4.3	1.2
DP11: Fistula	7.6	1.1
DP12: Urinary tract infection (bacteriuria, pyuria, treated with antibiotics)	3.5	1.1
DP13: Bleeding, reoperation required	7.5	1.2
DP14: Bleeding, transfusion required	5.6	1.5
DP15: Bleeding, observation only	3.6	1.5
DP16: Reoperation because of an unrecognized bladder injury	7.0	1.1
DP17: Reoperation because of an unrecognized ureteral injury	7.7	1.2
DP18: Reoperation because of an unrecognized bowel injury	8.5	1.1
DP19: Reoperation because of any other complication of original surgery	7.4	1.0
DP20: Pneumonia	5.7	1.5
DP21: Pulmonary edema	5.9	1.5
DP22: Mental status changes, dementia	6.0	1.7
DP23: Pelvic abscess	6.7	1.4
DP24: Sepsis, disseminated intravascular coagulation	9.0	1.1
DP25: Readmission secondary to a complication of original surgery	6.3	1.4
DP26: Graft erosion that requires surgical excision	6.0	1.4
DP27: Graft erosion trimmed in office	4.1	1.1
DP28: Graft erosion expectantly managed	3.3	1.2
DP29: Suture erosion	3.5	1.1
DP30: Urinary retention that requires surgical revision.	6.1	1.3
DP31: Prolonged urinary retention (>4 wk) that requires catheterization	4.7	1.3
DP32: Transient urinary retention (<4 wk)	3.2	1.3
DP33: Persistent neuropathy at (≥6 wk)	7.1	1.5
DP34: Granulation tissue	3.1	1.2

Disclaimer: This scale is not ready for clinical or research use in its current form. It is under revision; a simplified version will be published with instructions regarding usage once it has been validated.

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more severe complications. Grade I includes complications requiring no medications or specific medications and wound infections treated at the bedside. Grade II includes other medications, blood transfusions, and total parenteral nutrition. Grade III requires surgical, endoscopic, or radiologic management and grade IV involves life-threatening complications with intermediate or intensive care unit treatment. Grade V includes patient death.[2] The modified version of this scale was used according to the original specifications with 1 exception: complications were also categorized during surgery and at time periods after discharge. Clavien-Dindo scores for SISTEr subjects were calculated for all delayed postoperative complications; Clavien-Dindo scores for CARE subjects were calculated for only those delayed postoperative complications that were believed to be associated with the original surgery.

We then examined associations between PFCS composite scores and LOH, QoL, and satisfaction at 3 months with general linear fit models (LOH, HUI, and SF-36) and ordinal logistic regression for satisfaction. Because UDI and IIQ had a large proportion of subjects with 0 values, a 2-step analysis was run. The first step used a logistic model to evaluate the association between a PFCS composite score and a dichotomous UDI score (0 vs scores >0). The second step used a general linear model to evaluate the association between PFCS composite score and UDI score for all subjects with a UDI score >0 (log [e-base] transformed before analysis). Each analysis was adjusted for the corresponding baseline QoL scores when available (HUI, SF-36, UDI, and IIQ). We chose to analyze the 2 studies (CARE and SISTEr) as 1 combined group because the goal of this study was to evaluate the PFCS among various patients who had undergone reconstructive pelvic surgery. Because the 2 study populations and types of procedures were inherently different, we also adjusted each analysis for the study (CARE and SISTEr). We performed similar analyses for Clavien-Dindo score at 3 months. In addition, we examined associations between PFCS and Clavien-Dindo 1-year scores and 1-year outcomes. In all analyses, PFCS was treated as a continuous variable, and Clavien-Dindo was treated as a categoric variable. The associations for PFCS and Clavien-Dindo scores were compared with the use of Pearson and Spearman correlation coefficients (R-square) or Akaike Information Criterion. A probability value of $< .05$ was considered statistically significant.

RESULTS

Scale development

Forty-seven surgeons participated, which yielded a mean score and standard deviation for each complication (Table 1). The highest score was 9.0 for sepsis/disseminated intravascular coagulation and lowest 2.3 for postoperative fever that did not require antibiotics. Standard deviations ranged from 0.7–1.7 for all complications.

Demographics and scale assessment

Participants included 977 women (CARE, 322 women; SISTEr, 655 women); baseline characteristics and surgical information are listed in Table 2. Mean age was 55 years, and mean body mass index was 29 kg/m^2. Most of the women were non-Hispanic white (79%), married (71%), and menopausal (75%) and had had pelvic surgery (70%). Most women had stage 2 or 3 prolapse (44% and 31%, respectively). Median LOH was 2 days (quartile range, 1–3 days). Table 3 contains the QoL measures at baseline, 3 months and 1 year plus satisfaction at 3 months and 1 year. All variables improved from baseline, and 90% of the women were somewhat or very satisfied at 3 months.

At 3 months, the mean PFCS composite score was 2.1 $\pm$ 3.6, and 63% of the women did not have any complications (score, 0). For the same time period, 57% of the women were assigned a modified Clavien-Dindo grade 0; 9% were assigned grade 1; 29% were assigned grade 2; 4% were assigned grade 3; and 1% were assigned grade 4. Tables 4 and 5 show the results of the association analysis between LOH, QoL, and satisfaction and Clavien-Dindo and PFCS scores at 3 months. Results from linear and logistic regression are included in each table. Because of limited space, we did not show the effect of confounders that were controlled in each model (ie, study effect and baseline QoL scores). At 3 months, higher PFCS scores were associated with longer LOH ($P < .01$) and decreased QoL outcomes: lower HUI ($P < .01$), lower SF-36 physical component summary score ($P = .03$), higher pelvic floor symptom distress and impact (UDI [$P < .01$], IIQ [$P < .01$]), and lower satisfaction ($P < .01$). Clavien-Dindo scores were associated with LOH ($P < .01$), HUI ($P < .01$), SF-36 physical component summary score ($P = .02$), UDI ($P = .02$), IIQ ($P = .04$), and satisfaction ($P < .01$). The SF-36 mental component summary score was not associated significantly with either PFCS composite score or modified Clavien-Dindo score at 3 months. The PFCS composite and modified Clavien-Dindo scores are very similar in terms of their association with LOH, QoL measures, and satisfaction when R-square (0.74 to 0.93 at 3 months and 1 year) and Akaike Information Criterion values are compared. Neither the PFCS nor the modified Clavien-Dindo scores were associated with any of the 1 -year postoperative outcomes (LOH, QoL, or satisfaction).

COMMENT

This study was undertaken because current validated surgical complication scales do not capture the magnitude and consequence of complications for women who undergo pelvic reconstructive surgery for prolapse and urinary incontinence. Therefore, a group of expert pelvic surgeons who are participating in large, multicenter clinical trials developed a new measure of surgical complications that is intended to reflect bother, severity, and duration of disability in women as continuous measures both during surgery and for 3 months after surgery. It is designed for all routes of pelvic surgery (vaginal, laparoscopic/robotic, and open) and characterizes unique complications that have been encountered with prolapse and incontinence procedures, which includes those that involve blind passes of trocars and

TABLE 2
Baseline characteristics and surgical information

Variable	Measure
Age, n[a]	54.9 ± 11.1
Body mass index, kg/m^2[a]	29.0 ± 5.8
Race, n (%)	
Non-Hispanic white	774 (79.3)
Hispanic	81 (8.3)
Non-Hispanic black	60 (6.1)
Non-Hispanic other	61 (6.3)
Marital status, n (%)	
Married or living as married	687 (70.7)
Separated, divorced, widowed	285 (29.3)
Education, n (%)	
Completed ≥4 years of college	242 (24.8)
Some college/Associate degree	358 (36.6)
Less than or equivalent to complete high school	377 (38.6)
Current tobacco use, n (%)	116 (11.9)
Menopause, n (%)	
After menopause	735 (75.3)
Before menopause	241 (24.7)
Previous pelvic surgery, n (%)	684 (70)
Diabetes mellitus, n (%)	62 (6.3)
Pelvic organ prolapse quantification examination, n (%)	
Stage 0	30 (3.1)
Stage 1	132 (13.5)
Stage 2	431 (44.1)
Stage 3	305 (31.2)
Stage 4	79 (8.1)
Surgery route, n (%)	
Combined abdominal and vaginal	521 (53.3)
Abdominal	456 (46.7)
Type of anesthesia, n (%)	
General	851 (87.1)
Other	126 (12.9)
Length of surgery, min[a]	151.4 ± 67.1

[a] Data are given as mean ± SD.

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prosthetic graft material, which are not measured in currently validated surgery complication scales.

The Clavien-Dindo scale is the best described surgical complication classification scale to categorize perioperative complications reliably and to facilitate comparison of surgical outcomes; however, it is oriented to general surgery procedures.[9] Although this scale has many strengths, we were concerned that it may not reflect the complication profile of pelvic reconstructive procedures, which generally are performed electively on medically optimized women as an outpatient (same day) surgery or with short (1- to 2-day) inpatient hospitalization. Additionally, the Clavien-Dindo scale was validated in a cohort of men and women, but women often rated complications as less severe than men, which suggests that the scale may perform differently in women.[3] Our study shows that the Clavien-Dindo scale performed similarly to a more specific scale (PFCS). This is reasonable because surgical complications have some common denominator.

On face value, the categoric Clavien-Dindo scale seemed less conducive to comparison of morbidity among urogynecologic procedures. For example, urinary tract infection (a common complication after pelvic reconstructive surgery) is scored disproportionately higher on the scale than wound complications. We intended to develop a morbidity scale that ultimately could be used to compare traditional and emerging technologies and approaches comprehensively. The CARE and SISTEr studies involved traditional surgeries but did not compare them to emerging technologies and minimally invasive approaches. Future evaluation of the PFCS in women who undergo transvaginal mesh repair or laparoscopic sacral colpopexy may prove valuable. This is highly relevant in light of recent Food and Drug Administration warnings about the transvaginal use of mesh for prolapse procedures.[10]

The CARE and SISTEr trial datasets of clinical and QoL outcomes provided an opportunity to calculate PFCS scores retrospectively on well-characterized populations of women who had had pelvic surgery for urinary incontinence and/or prolapse. The calculated composite PFCS score was associated with clinical measures that reflected adverse outcomes that included longer LOH, decreased QoL, and decreased overall satisfaction at 3 months. However, we were surprised to find that the enhanced complication details that were provided by the PFCS did not strengthen associations with bother and QoL measures at 3 months, when compared with the modified Clavien-Dindo scale. Both scales showed limited overall predictive value. The moderate association may reflect

TABLE 3
Quality-of-life measures and satisfaction

Outcome	Baseline	3 mo	1 y
Urogenital Distress Inventory score[a]	121.7 ± 62.5 (n = 966)	29.5 ± 36.9 (n = 900)	29.0 ± 37.4 (n = 816)
Incontinence Impact Questionnaire score[a]	136.6 ± 104.7 (n = 968)	43.8 ± 73.6 (n = 900)	27.5 ± 56.3 (n = 814)
Health Utilities Index score[a]	0.7 ± 0.3 (n = 648)	0.8 ± 0.2 (n = 633)	0.8 ± 0.3 (n = 512)
Short Form-36 score[a]			
Physical	45.4 ± 9.6	47.0 ± 8.8	49.3 ± 9.3
Mental	51.9 ± 8.9 (n = 315)	53.0 ± 9.3 (n = 304)	53.1 ± 8.8 (n = 304)
Satisfaction, n (%)			
Very satisfied		607 (68.0)	556 (68.2)
Somewhat satisfied		196 (21.9)	166 (20.4)
Neither satisfied nor dissatisfied		27 (3.0)	22 (2.7)
Somewhat dissatisfied		36 (4.0)	52 (6.4)
Very dissatisfied		27 (3.0)	19 (2.3)

[a] Data are given as mean ± SD.

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discordance between surgeon-designed measures of morbidity and the patients' subjective experience and tolerance of the complication. Clavien et al[3] found important differences in physician and patient perceptions of complication severity when they asked physicians and patients to score 30 hypothetic scenarios on a numeric rating scale from 0-100. Patients perceived many complications to be more severe than did physicians. In another prospective study, patients were more likely to consider events to be complications compared with surgeons (44% of patients vs 8% of surgeons reported a perioperative complication).[11] Patients frequently cited common perioperative events, such as constipation and temporary urinary catheterization, to be complications.

The PFCS and Clavien-Dindo scales had similar associations with clinical measures of morbidity and QoL. The authors who generated the respective scores considered the modified Clavien-Dindo scale to be easier to apply. They found the assignment of PFCS scores to

TABLE 4
Associations between scales with length of hospitalization, quality of life, and satisfaction and 3 month outcome measures

Variable	Length of hospitalization: regression coefficient (95% CI)[a]	Health Utilities Index: regression coefficient (95% CI)[a]	Short Form-36: regression coefficient (95% CI)[a]		Satisfaction: odds ratio (95% CI)[b]
			Mental	Physical	
Clavien-Dindo score (0 as reference)					
Grade IV	3.9 (3.1–4.8)	−0.2 (−0.4 to 0.04)	−6.7 (−18.1 to 4.8)	−1.3 (−11.6 to 9.0)	0.3 (0.1–1.2)
Grade III	0.7 (0.4–1.1)	−0.02 (−0.1 to 0.1)	−3.0 (−6.8 to 0.8)	−0.7 (−4.1 to 2.7)	0.2 (0.1–0.4)
Grade II	0.5 (0.4–0.7)	−0.03 (−0.1 to 0)	−1.7 (−4.0 to 0.7)	−2.6 (−4.7 to −0.5)	0.7 (0.5–0.9)
Grade I	0.2 (−0.1 to 0.4)	−0.1 (−0.1 to 0)	−1.1 (−4.2 to 1.9)	−4.1 (−6.8 to −1.4)	0.7 (0.4–1.1)
P value[c]	< .01	< .01	.29	.02	< .01
Pelvic Floor Complication Scale					
Change per 10 units of Pelvic Floor Complication Scale score	1.1 (0.9–1.3)	−0.1 (−0.1 to −0.05)	−1.7 (−4.4 to 1.0)	−2.7 (−5.3 to −0.2)	0.5 (0.4–0.7)
P value	< .01	< .01	.21	.03	< .01

CI, confidence interval.

[a] Linear regression; [b] Ordinal logistic model; [c] For linear regression, this is the probability value for the omnibus F-test; for ordinal logistic models, this is the probability value for the Wald χ^2 statistics.

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TABLE 5
Associations between scales with UDI and the IIQ and 3 month outcome measures

	Urogenital Distress Inventory		Incontinence Impact Questionnaire	
Variable	**>0 vs = 0[a]**	**>0[b]**	**>0 vs = 0[a]**	**>0[b]**
Clavien-Dindo grade (0 as reference)				
IV	0.45 (0.1–2.7)	2.2 (0.7–6.8)	2.1 (0.7–6.2)	2.9 (0.3–33.0)
III	9.0 (1.2–66.8)	1.4 (0.9–2.3)	1.4 (1.0–2.0)	2.1 (0.8–5.3)
II	1.7 (1.1–2.6)	1.3 (1.0–1.6)	1.2 (1.0–1.4)	1.3 (0.9–2.1)
I	1.3 (0.7–2.6)	1.3 (0.9–1.9)	1.0 (0.7–1.3)	0.8 (0.5–1.4)
P value[c]	.02	.12	.11	.11
Pelvic Floor Complication Scale				
Odds ratio for 10 units change of Pelvic Floor Complication Scale score	1.5 (0.8–2.4)	1.5 (1.1–2.0)	1.3 (1.1–1.7)	1.6 (1.0–2.4)
P value	.19	< .01	< .01	.02

CI, confidence interval; *IIQ*, Incontinence Impact Questionnaire; *UDI*, Urogenital Distress Inventory.

[a] Linear model: odds ratio (95% CI); [b] Linear regression: exp(regression coefficient) (95% CI); these analyses were based on log (e-base) transformed scores and the listed numbers should be interpreted as multiplicative effect (for instance, among those who had Urogenital Distress Inventory scores of >0, the mean score of Urogenital Distress Inventory for a subjects whose Clavien-Dindo grade equals IV is approximately 2.2 times as high as those whose Clavien-Dindo grade equals 0); [c] for linear regression, this is the probability value for the omnibus F-test; for logistic regression, this is the probability value for the Wald χ^2 statistics.

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be complex, especially in the setting of wound complications because nearly 25% of the PFCS scores required adjudication. The retrospective acquisition of morbidity details may have contributed to their difficulty.

The potential strength of this PFCS measure is that it is oriented specifically towards pelvic reconstructive surgery in women. We believe it more accurately classifies urinary tract infections and gives greater weight to wound complications, especially vaginal mesh exposure, and to the sequelae of dyspareunia and other types of pelvic pain, regardless of implementation of therapy for the pain. However, its potential as a sensitive tool with prospective use in comparative studies has yet to be determined.

The specific nature of the PFCS may limit its ability to compare complications across different surgical disciplines that are relative to the Clavien-Dindo scale. Another limitation involves the more complex statistical analysis that is required to compare a continuous scale (PFCS) to a categoric scale (Clavien-Dindo), which may be more difficult to understand. We believed it important to analyze the PFCS in the way in which it was intended to be used, as a continuous scale score with a cumulative complication effect. We believe that this will reflect the overall severity and patient bother better, but we must investigate this further using patient-centered outcomes.

Although the PFCS items and scoring system were developed by 47 surgeons, the scale was not tested further in a general population of surgeons before we used it in our study. Further, our results may not be generalizable for other populations because the SISTEr and CARE populations are predominantly white, married, educated, and nonsmokers. Generic QoL measures were not the same in both studies. The surgical approaches in the 2 trials did not include today's more commonly performed synthetic mesh mid urethral slings, vaginal mesh or graft placement, or minimally invasive robotic and laparoscopic approaches to sacral colpopexy.

Future prospective studies are necessary to evaluate and validate the scale.

To improve the utility and applicability of the PFCS, future developmental efforts should simplify the measure and still incorporate outpatient treatment of complications. It would be reasonable to shorten the PFCS scale by collapsing the immediate and delayed postoperative complication categories because we collect the timing of the complication; most of the 24 overlapping complications have similar scores. We also would include complications that are omitted among the initial 73 complication that are included (such as emergency room or unplanned office visits) and factor in patients' perceptions of complications. The assignment of PFCS score prospectively will provide information on the ease of use and reproducibility. Because most of the complications occurred within the first 3 months after surgery and 12-month scores were not correlated with QoL measures, we recommend that the composite 3-month score be the sole score.

In summary, despite the fact that the Clavien-Dindo scale does not account for complications that are diagnosed after discharge, both the PFCS and modified Clavien-Dindo scale seemed to possess similar associations with the outcomes that were tested in women during the initial 3 months after pelvic reconstructive surgery. Based on our results, the modified Clavien-Dindo scale appears to be a useful complication scale in women who undergo and for 3 months after pelvic reconstructive surgery. This initial version of the PFCS has the potential to reflect complica-

tions that are specific to pelvic floor surgery, compared with the Clavien-Dindo scale. Further refinements to the scale are planned to streamline its use prospectively in future trials. ■

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