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The Pelvic Floor Complication Scale: A New Instrument for Reconstructive Pelvic Surgery

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Abstract

Objective—To develop and test a unique, new pelvic floor surgery complication scale and compare it to an existing validated measure.

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Study Design—Surgeons from two 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 two multicenter pelvic floor surgical trials. The PFCS and modified Clavien-Dindo scores were evaluated for associations with length of hospitalization(LOH), satisfaction, and quality-of-life (QoL) measures {Health Utilities Index(HUI), Short Form-36(SF-36), Urogenital Distress Inventory(UDI) and Incontinence Impact Questionnaire(IIQ)}.

Results—We calculated PFCS scores for 977 subjects. Higher PFCS and Clavien-Dindo scores were similarly associated with longer LOH ($p<0.01$), lower satisfaction ($p<0.01$); lower HUI ($p=0.02$), lower SF-36 ($p=0.02$), higher UDI ($p<0.01$) and IIQ ($p<0.01$) scores at 3 months. No associations were present at 1 year.

Conclusion—The PFCS compares favorably to the validated modified Clavien-Dindo instrument.

Key Words/Phrases

Complications; Reconstructive Pelvic Surgery; Urogynecology; Surgical Outcomes; Quality-of-life measures; Clavien-Dindo

Introduction

Pelvic floor disorders, like pelvic organ prolapse and urinary incontinence, often impair a woman's quality of life but rarely, in themselves, result in significant morbidity or mortality. The surgical procedures used to correct these conditions impart some risk of morbidity.¹ Given this, patients and physicians must carefully weigh 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 anatomical and symptomatic improvement but increased morbidity may not be as desirable as a surgery that has good anatomical 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 one of several groups and are intended for use in all surgical disciplines. The Clavien-Dindo system classifies complications into one of 4 categories based on the type of therapy needed to correct the complication.² This system is reproducible, easy to apply, has been validated compared to complexity of surgery and length of hospital stay in general surgery populations, and has been recently used in several studies evaluating pelvic reconstructive procedures.⁵⁻⁸ However, current systems are not condition specific and do not take into account the unique complications associated with pelvic reconstructive surgery. The objective of this study was to develop a peri- and postoperative complication scale specific to pelvic reconstructive surgery and compare its ability to predict factors associated with perioperative morbidity to the Clavien-Dindo system.

Materials and Methods

Investigators from the Pelvic Floor Disorders Network (PFDN) and the Urinary Incontinence Treatment Network (UITN) rated specific intraoperative plus immediate and delayed postoperative complications on a scale from 0 to 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 obtained. (Appendix A)

PFCS scores were retrospectively calculated 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 women⁶ 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 lacking 3-month follow up data. Complications for each study had already been evaluated, 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 listed in Appendix A to use as a guide for cases in which the information from the database was insufficient to categorize the complication. 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 related to the complication was selected.

Two independent investigators reviewed all complications that occurred during the first year postoperatively 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 months (discharge to 90 days) postoperative, and 1 year (91 to 365 days) postoperative. Complications that were being actively managed over more than one 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 postoperative. Individual complication scores for each time period were summed. We defined the PFCS composite score as the sum of all complications occurring during the perioperative and 3 month postoperative time periods. Medical complications that were > 6 weeks postoperative and were not felt by 3 reviewers to be related to the original surgery did not receive a PFCS score.

Patient demographics collected included age, race, marital status, education, tobacco use, menopause, prior pelvic surgery, diabetes, body mass index (BMI), and preoperative pelvic organ prolapse quantification exam (POP-Q) stage. Quality-of-life (QoL) measures including 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 ranges from 0 to 1 with higher value indicating better health but scores can also be negative (lowest possible value=-0.36), which reflects health states considered worse than death. The mental (MCS) and physical component summary (PCS) scores of the SF-36 range from 0 to 100 with higher scores indicating better health. UDI scores range from 0 to 300 and IIQ scores range from 0 to 400 with higher scores indicating worse QoL. Satisfaction was

measured using a global satisfaction question with 5 point Likert scale from very dissatisfied to very satisfied at 3 months and 1 year. Additionally, surgical information including route of surgery, type of anesthesia, length of surgery, and postoperative length of hospitalization (LOH) was obtained.

Complications were also assessed using a modified Clavien-Dindo scale.² The original Clavien-Dindo scale was validated for immediate postoperative complications prior to discharge in a general surgical population. The scale ranges from grade I to IV with higher scores indicating 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. (Table 1 from reference ²) The modified version of this scale was used according to the original specifications with one 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 only for those delayed postoperative complications felt to be associated with the original surgery.

We then examined associations between PFCS composite scores and LOH, QoL and satisfaction at 3 months using general linear fit models (LOH, HUI, and SF-36) and ordinal logistic regression for satisfaction. Since UDI and IIQ had a large proportion of subjects with 0 values, a two-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 versus 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 prior to analysis). Each analysis was adjusted for the corresponding baseline QoL scores when available (HUI, SF-36, UDI, and IIQ). We chose to analyze the two studies (CARE and SISTER) as one combined group since the goal of this study was to evaluate the PFCS among various patients undergoing reconstructive pelvic surgery. Since the two study populations and types of procedures were inherently different, we also adjusted each analysis for study (CARE and SISTER).

We performed similar analyses for Clavien-Dindo 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 as a categorical variable. The associations for PFCS and Clavien-Dindo were compared using Pearson and Spearman correlation coefficients (R-square) or Akaike Information Criterion (AIC). A p-value of < 0.05 was considered statistically significant.

Results

Scale development

Forty-seven surgeons participated yielding a mean score and standard deviation for each complication (Appendix A). The highest score was 9.0 for sepsis/disseminated intravascular coagulation and lowest 2.3 for postoperative fever not requiring antibiotics. Standard deviations ranged from 0.7 to 1.7 for all complications.

Demographics and Scale assessment

Participants included 977 women (322 CARE and 655 SISTER); baseline characteristics and surgical information are listed in Table 1. Mean age was 55 years old and mean BMI was 29. The majority were non-hispanic white (79%), married (71%), menopausal (75%), and

had prior pelvic surgery (70%). Most had stage 2 or 3 prolapse (44% and 31%, respectively). Median length of hospitalization was 2 days (quartile range 1–3 days). Table 2 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 women were somewhat or very satisfied at 3 months.

At 3 months, the mean PFCS composite score was 2.1 (± 3.6) and 63% of subjects did not have any complications (score = 0). For the same time period, 57% of women were assigned a modified Clavien-Dindo grade 0, 9% grade 1, 29% grade 2, 4% grade 3, and 1% grade 4. Table 3 and 4 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. Due to limited space, we did not show the effect of confounders that were controlled in each model (i.e. study effect and baseline QoL scores). At 3 months, higher PFCS scores were associated with longer LOH ($p < 0.01$) and decreased QoL outcomes: lower HUI ($p < 0.01$), lower SF-36 PCS score ($p = 0.03$), higher pelvic floor symptom distress and impact (UDI ($p < 0.01$), IIQ ($p < 0.01$)) and lower satisfaction ($p < 0.01$). Clavien-Dindo scores were similarly associated with LOH ($p < 0.01$), HUI ($p < 0.01$), SF-36 PCS score ($p = 0.02$), UDI ($p = 0.02$), IIQ ($p = 0.04$), and satisfaction ($p < 0.01$). The SF-36 MCS score was not significantly associated 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 comparing R-square (0.74 to 0.93 at 3 months and 1 year) and AIC values. 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 undergoing pelvic reconstructive surgery for prolapse and urinary incontinence. Therefore, a group of expert pelvic surgeons participating in large, multicenter clinical trials developed a new measure of surgical complications intended to reflect bother, severity and duration of disability in women as continuous measures both intraoperatively and for 3 months postoperatively. It is designed for all routes of pelvic surgery (vaginal, laparoscopic/robotic and open) and characterizes unique complications encountered with prolapse and incontinence procedures, including those involving blind passes of trocars and 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 reliably categorize peri-operative complications and facilitate comparison of surgical outcomes; however, it is oriented to general surgery procedures.⁹ While this scale has many strengths, we were concerned that it may not reflect the complication profile of pelvic reconstructive procedures, which are generally electively performed 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 suggesting 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 as surgical complications have some common denominator.

On face value, the categorical Clavien-Dindo Scale seemed less conducive to comparing morbidity amongst 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 could ultimately be used to comprehensively compare traditional and emerging technologies and approaches. 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 undergoing transvaginal mesh repair or laparoscopic sacral colpopexy may prove valuable. This is highly relevant in light of recent FDA warnings about transvaginal use of mesh for prolapse procedures.¹⁰

The CARE and SISTER trial datasets of clinical and QoL outcomes provided an opportunity to retrospectively calculate PFCS scores on well characterized populations of women who had pelvic surgery for urinary incontinence and/or prolapse. The calculated composite PFCS score was associated with clinical measures that reflect adverse outcomes including longer length of hospitalization, decreased quality-of-life and decreased overall satisfaction at 3 months. However, we were surprised to find that the enhanced complication details provided by the PFCS did not strengthen associations with bother and quality of life measures at 3 months when compared to the modified Clavien-Dindo scale. Both scales showed limited overall predictive value. The moderate association may reflect discordance between surgeon-designed measures of morbidity and the patients' subjective experience and tolerance of the complication. Clavien et al found important differences in physician and patient perceptions of complication severity when they asked physicians and patients to score 30 hypothetical scenarios on a numerical rating scale from 0–100.³ Patients perceived many complications as more severe than physicians. In another prospective study, patients were also more likely to consider events to be complications compared to surgeons (44% of patients versus 8% of surgeons reported a peri-operative complication).¹¹ Patients frequently cited common peri-operative events, such as constipation and temporary urinary catheterization, as 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 easier to apply. They found assignment of PFCS scores to be complex especially in the setting of wound complications with nearly 25% of the PFCS scores requiring adjudication. The retrospective acquisition of morbidity details may have contributed to their difficulty.

The potential strength of this PFCS measure is that it is specifically oriented towards pelvic reconstructive surgery in women. We believe it more accurately classifies urinary tract infections while giving greater weight to wound complications especially vaginal mesh exposure, and 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 relative to the Clavien-Dindo scale. Another limitation involves the more complex statistical analysis required to compare a continuous scale (PFCS) to a categorical scale (Clavien-Dindo), which may be more difficult to understand. We felt 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 this will better reflect the overall severity and patient bother, but need to investigate this further using patient centered outcomes.

While the PFCS items and scoring system were developed by 47 surgeons, the scale was not further tested in a general population of surgeons before we used it in our study. Further, our results may not be generalizable for other populations as the SISTER and CARE populations

are predominantly Caucasian, married, educated and nonsmokers. Generic QoL measures were not the same in both studies. The surgical approaches in the two trials did not include today's more commonly performed synthetic mesh midurethral 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 while still incorporating outpatient management of complications. It would be reasonable to shorten the PFCS scale by collapsing the immediate and delayed postoperative complication categories since we collect the timing of the complication and the majority of the 24 overlapping complications have similar scores. We also would include complications omitted amongst the initial 73 included (such as emergency room or unplanned office visits) and factor in patients' perceptions of complications. Assignment of PFCS score prospectively will provide information on ease of use and reproducibility. Since 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 diagnosed after discharge, both the PFCS and modified Clavien-Dindo scale seemed to possess similar associations with the outcomes 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 undergoing and for 3 months following pelvic reconstructive surgery. This initial version of the PFCS has the potential to reflect complications specific to pelvic floor surgery as compared to the Clavien-Dindo scale. Further refinements to the scale are planned to streamline its use prospectively in future trials.

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Appendix A. Pelvic Floor Complication Scale: Peri- and Postoperative Morbidity with physician rated complication severity levels

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

MORBIDITY	Mean	SD
<i>Intraoperative (Before Leaving Operating Room)</i>		
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 requiring vascular surgeon	7.7	1.3
OR5: Ureteral injury requiring reanastomosis	7.0	0.9
OR6: Ureteral injury requiring stent	5.8	1.3
OR7: Ureteral injury 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 >1000cc	5.3	1.7
OR11: Urethral injury	5.8	1.3
OR12: Cystotomy requiring repair	4.7	1.2
OR13: Cystotomy not requiring repair	3.1	1.2
<i>Immediately postoperative (After Leaving Operating Room to Discharge)</i>		
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 (etiology uncertain)	3.6	1.3
IP5: Post-operative fever requiring antibiotics (etiology uncertain)	3.5	1.1
IP6: Post-operative fever resolving 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 - no dehiscence (cellulitis resolved with antibiotics)	4.0	0.9

MORBIDITY	Mean	SD
IP11: Fistula	7.5	1.3
IP12: Neuropathy persistent at time of discharge	6.0	1.6
IP13: Neuropathy resolves prior to 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 due to an unrecognized bladder injury	6.9	0.9
IP19: Reoperation due to an unrecognized ureteral injury	7.6	0.9
IP20: Reoperation due to an unrecognized bowel injury	8.3	1.0
IP21: Reoperation due to any other complication of original surgery	7.2	0.9
IP22: Pneumonia	5.7	1.4
IP23: Pulmonary edema	5.9	1.5
IP24: Mental status changes	6.0	1.6
IP25: Pelvic abscess	6.6	1.5
IP26: Sepsis, Disseminated intravascular coagulation	9.0	1.1
<i>Delayed postoperative (After Discharge)</i>		
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 (etiology uncertain)	4.3	1.5
DP5: Post-operative fever requiring antibiotics (etiology uncertain)	4.1	1.1
DP6: Post-operative fever resolving 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 due to an unrecognized bladder injury	7.0	1.1
DP17: Reoperation due to an unrecognized ureteral injury	7.7	1.2
DP18: Reoperation due to an unrecognized bowel injury	8.5	1.1
DP19: Reoperation due to 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

MORBIDITY	Mean	SD
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 requiring 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 requiring surgical revision.	6.1	1.3
DP31: Prolonged urinary retention (>4weeks) requiring catheterization	4.7	1.3
DP32: Transient urinary retention (<4weeks)	3.2	1.3
DP33: Persistent neuropathy at (6weeks)	7.1	1.5
DP34: Granulation tissue	3.1	1.2

SD: Standard Deviation

Table 1

Baseline characteristics and surgical information

Variable	Mean (SD) or N (%)
Age	54.9 (+/-11.1)
BMI	29.0 (+/-5.8)
Race	
Non-Hispanic white	774 (79.3%)
Hispanic	81 (8.3%)
Non-Hispanic black	60 (6.1%)
Non-Hispanic other	61 (6.3%)
Marital Status	
Married or living as married	687 (70.7%)
Separated, divorced, widowed	285 (29.3%)
Education	
Completed 4 years of college or more	242 (24.8%)
Some college/Associate degree	358 (36.6%)
Less than or equivalent to complete high school	377 (38.6%)
Current tobacco use	116 (11.9%)
Menopause	
post-menopause	735 (75.3%)
pre-menopause	241 (24.7%)
Previous pelvic surgery	684 (70%)
Diabetes	62 (6.3%)
POP-Q	
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	
Combined abdominal and vaginal	521 (53.3%)
Abdominal	456 (46.7%)
Type of anesthesia	
General	851 (87.1%)
Other	126 (12.9%)
Length of surgery (minutes)	151.4 (+/-67.1)

SD: Standard Deviation

N: Number

Table 2

Quality-of-life measures and satisfaction

Outcome	Baseline	3 Months	1 Year
Urogenital Distress Inventory	121.7 (+/-62.5) N = 966	29.5 (+/-36.9) N = 900	29.0 (+/-37.4) N = 816
Incontinence Impact Questionnaire	136.6 (+/-104.7) N = 968	43.8 (+/-73.6) N = 900	27.5 (+/-56.3) N = 814
Health Utilities Index	0.7 (+/-0.3) N = 648	0.8 (+/-0.2) N = 633	0.8 (+/-0.3) N = 512
Short Form-36			
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			
Very Satisfied		607 (68%)	556 (68.2%)
Somewhat Satisfied		196 (21.9%)	166 (20.4%)
Neither satisfied nor dissatisfied		27 (3%)	22 (2.7%)
Somewhat Dissatisfied		36 (4%)	52 (6.4%)
Very Dissatisfied		27 (3%)	19 (2.3%)

All results presented as mean plus standard deviations except for satisfaction, which is the number and percentage.

N: Number

Table 3

Associations between Clavien-Dindo and PFCS composite scores with length of hospitalization, quality of life, and satisfaction at 3 months.

		LOH*	HUI*	SF-36* Mental	SF-36* Physical	Satisfaction [‡]
Clavien-Dindo Score(0 as reference)	IV	3.9 (3.1,4.8)	-0.2 (-0.4,0.04)	-6.7 (-18.1,4.8)	-1.3 (-11.6,9.0)	0.3(0.1,1.2)
	III	0.7 (0.4,1.1)	-0.02 (-0.1, 0.1)	-3.0 (-6.8,0.8)	-0.7 (-4.1,2.7)	0.2(0.1,0.4)
	II	0.5 (0.4,0.7)	-0.03 (-0.1,0)	-1.7 (-4.0,0.7)	-2.6 (-4.7, -0.5)	0.7(0.5,0.9)
	I	0.2 (-0.1,0.4)	-0.1 (-0.1,0)	-1.1 (-4.2,1.9)	-4.1 (-6.8, -1.4)	0.7(0.4,1.1)
	P- value [‡]	<0.01	<0.01	0.29	0.02	<0.01
PFCS	Change per 10 units of PFCS score	1.1 (0.9, 1.3)	-0.1 (-0.1, -0.05)	-1.7 (-4.4,1.0)	-2.7 (-5.3, -0.2)	0.5 (0.4,0.7)
	P-value	<0.01	<0.01	0.21	0.03	<0.01

LOH = Length of hospitalization, HUI = Health Utilities Index

* Linear Regression: Regression Coefficient (95% CI)

[‡] Ordinal Logistic Model: Odds Ratio (95% CI)

[‡] For linear regression, this is the p-value for the omnibus F-test; for ordinal logistic models, this is the p-value for the Wald χ^2 statistics.

Table 4
Associations between Clavien-Dindo and PFCS composite scores with UDI and IIQ at 3 months.

	UDI		IIQ	
	UDI>0 vs. UDI=0*	UDI >0 [‡]	IIQ>0 vs. IIQ=0*	IIQ >0 [‡]
Clavien-Dindo Score (0 as reference)	IV	0.45 (0.1,2.7)	2.2 (0.7, 6.8)	2.1 (0.7, 6.2)
	III	9.0 (1.2,66.8)	1.4 (0.9, 2.3)	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)
	I	1.3 (0.7,2.6)	1.3 (0.9, 1.9)	1.0 (0.7, 1.3)
	P-value [‡]	0.02	0.12	0.11
PFCS	OR for 10 units change of PFCS score	1.5 (0.8, 2.4)	1.5 (1.1, 2.0)	1.3 (1.1, 1.7)
	P-value	0.19	<0.01	<0.01
				0.02

UDI = Urogenital Distress Inventory, IIQ = Incontinence Impact Questionnaire, OR = Odds ratio

* Linear Model: OR (95% CI)

[‡]Linear Regression: Exp(Regression Coefficient) (95% CI). These analyses were done based on log (e-base) transformed scores and the listed numbers should be interpreted as multiplicative effect. For instance, among those who had UDI scores >0, the mean score of UDI for a subjects whose DINDO score equals to IV is approximately 2.2 times as high as those whose DINDO score equals to 0.

[‡]For linear regression, this is the p-value for the omnibus F-test; for logistic regression, this is the p-value for the Wald χ^2 statistics.