Long-term success of abdominal sacral colpopexy using synthetic mesh

Patrick J. Culligan, MD, Miles Murphy, MD, Linda Blackwell, BS, RN, Grant Hammons, MD, Carol Graham, MD, and Michael H. Heit, MD, MSPH

Louisville, Ky

OBJECTIVE: The aim was to determine the minimum meaningful study period required for prospective trials involving sacral colpopexy.

STUDY DESIGN: This is a retrospective analysis of 245 patients who underwent sacral colpopexy. Postoperative pelvic organ prolapse quantitation was our objective end point. In an effort to control for selection bias, patients who returned for postoperative examinations were compared with those who did not for clinical and demographic information. A validated prolapse-specific quality of life instrument was used to determine the subjective end points.

RESULTS: Objective failure (any postoperative POP-Q point ≥ stage II) was found in 37 (15.1%) patients. Of these, 26 (70.3%) occurred within 6 months, and 30 (81.1%) occurred within 1 year. Another 5 objective failures were discovered between 1 and 2 years after surgery for a total of 94.6% of failures occurring within 2 years. There were no clinically significant differences between the groups of women with and without objective postoperative follow-up, indicating minimal selection bias.

CONCLUSION: It is reasonable to construct randomized controlled trials involving sacral colpopexy that only include 1- or 2-year follow-up. (Am J Obstet Gynecol 2002;187:1473-82.)

Key words: Colpopexy, pelvic organ prolapse

The surgical correction of pelvic organ prolapse is fraught with challenges for physicians and patients alike. When recommending a particular operative approach, the surgeon must factor in the patient's health status, the precise defects responsible for her prolapse, and her future reproductive and/or sexual desires and expectations.

Although no specific operation can truly be considered the "gold standard," sacral colpopexy appears to be the most successful vaginal vault suspension operation.[1,2] Even though multiple long-term colpopexy studies cite prolapse cure rates of between 84% and 99%,[2-4] there is no such study that includes long-term results measured with objective prolapse assessment and validated quality-of-life measures.

Regardless of the surgical approach, the recovery period after reconstructive pelvic surgery involves significant morbidity, so informed consent for these operations should include the best possible information regarding long-term results for prolapse correction and symptom relief. Regrettably, there are few scientific data to draw on when counseling patients about the long-term subjective and objective cure rates after prolapse surgery.

There are several reasons for this lack of long-term information. Until recently, there were no standardized assessment tools with which to measure the success of prolapse surgery. With the publication of the International Continence Society system for pelvic organ prolapse quantification (the POP-Q system) in 1996, widespread standardized, objective reporting of prolapse was made possible for the first time.[5] Many groups are now working to validate prolapse symptom assessment tools as well. Current and future studies regarding prolapse surgery should include both objective outcomes measured with the POP-Q system as well as symptom relief and prolapse-related quality of life scores measured with reliable, validated instruments.[6]

But the availability of these research tools does not guarantee that patients will return for long-term follow-up. It is generally believed that clinical trials regarding these operations should be designed to include at least 5 years of follow-up because durability of pelvic reconstructive surgery deteriorates over time.[7]

However, others have argued that short-term follow-up may provide useful information. Shull et al[8] found that patients with normal support during an early postoperative visit were unlikely to have subsequent failures.

From the Division of Urogynecology and Reconstructive Pelvic Surgery, Department of Obstetrics, Gynecology, and Women's Health, University of Louisville Health Sciences Center.

Pesented at the Twenty-eighth Annual Meeting of the Society of Gynecologic Surgeons, Dallas, Tex, March 4-6, 2002.

Reprint requests: Patrick J. Culligan, MD, 315 E Broadway, M-18, Louisville, KY 40202. E-mail: pculligan@louisville.edu

0002-9378/2002 $35.00 + 0 ***6/6/129160***

doi:10.1067/mob.2002.129160

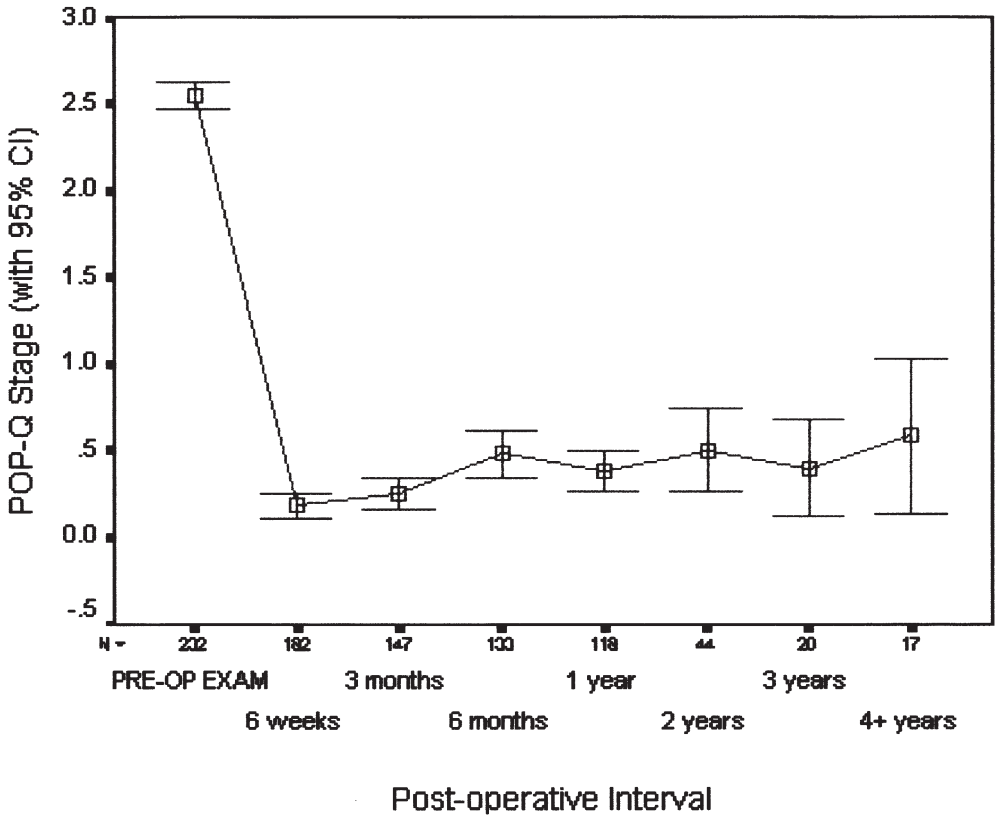

Fig 1. Preoperative and postoperative POP-Q stages.

When patients fail to return for long-term follow-up in any surgical study regarding prolapse, there is always the question: did they fail to come back because they were better, or because they had experienced a failure? In other words, to what extent did selection bias influence the study results?

The objective of this study was to establish the natural history of sacral colpopexy procedures performed with synthetic mesh. Our specific aim was to determine the minimum meaningful study period required for prospective trials including sacral colpopexy by controlling for selection bias.

Material and methods

Study design. A retrospective analysis was performed including all patients (n = 245) undergoing abdominal sacral colpopexy with synthetic mesh performed by members of the University of Louisville Health Sciences Center Division of Urogynecology and Reconstructive Pelvic Surgery. The operations were performed between September 11, 1994, and January 1, 2001. The surgical cases were identified by a combined review of our surgery schedule logs and hospital records. The University of Louisville Human Studies Committee approved the review and analysis of these records.

Operative technique. With the patient in Allen universal stirrups (Allen Medical Systems, Bedford Heights, Ohio), the prolapsed vaginal wall was replaced with an acrylic vaginal stent. The sigmoid colon was retracted laterally to the left pelvic sidewall, as the peritoneum of the right paracolic gutter was incised from sacral promontory to cul-de-sac. Sharp and blunt dissection was used to expose the anterior longitudinal ligament at the S2 to S3 level, and two to four permanent sutures were placed. Concomitant hysterectomy or salpingo-oophorectomy were performed before the sacral dissection when indicated. The vesicovaginal space was entered sharply, and the mesh was attached to the anterior vaginal wall with six to eight permanent sutures. A second piece of mesh was attached to the posterior vaginal wall with three to six rows of permanent sutures. The anterior mesh was then attached to the posterior mesh, which was then fastened to the sacral sutures without applying tension to the vaginal attachments. The peritoneum was then reapproximated over the mesh, and any other concomitant procedures were performed as indicated. Intraoperative cystoscopy was performed on all patients to assess ureteral function.

Outcome measures. Preoperative evaluations of these patients included urogynecologic history and physical

Table I. Prolapse symptom inventory (PSI) and quality-of-life scale (QOLS)

	All the time (4)	*Most of the time (3)*	*Some of the time (2)*	*Rarely (1)*	*Never (0)*
PART I: PSI					
1. I feel that I have to push or strain to empty the urine from my bladder.					
2. I assist my bladder to empty by placing a finger in the vagina or pressing on the skin outside of the vagina.					
3. I experience leakage of urine (incontinence) when I engage in activities such as coughing, sneezing, laughing, lifting, walking, or changing position.					
4. I rush to the bathroom so I will not leak urine.					
5. I wear protection (such as pads, diapers, or toilet paper) or change my undergarments to protect my clothes from urinary leakage.					
6. I experience constipation due to difficulty moving the stool out of my rectum.					
7. I assist myself to empty my bowels by placing a finger in the vagina.					
8. I experience incontinence of stool.					
9. I feel as though there is a "ball" between my legs or that I am sitting on a "ball."					
10. I feel a pressure in my vagina when standing which may lessen when lying down.					
11. Do you need to change positions or posture to help you empty your bladder?					
PART II: QOL					
12. Some or all of the symptoms, which are described above, *prevent me from pursuing new relationships with people.*					
13. Some or all of the symptoms, which are described above, *interfere with my sexual relationships.*					
14. Some or all of the symptoms, which are described above, *prevent me from engaging in physical recreation (dancing, sports, etc).*					
15. Some or all of the symptoms, which are described above, *prevent me from engaging in nonstrenuous leisure activities (eating out, going to a show, etc).*					

Table II. Demographics of study population (n = 245)

Age (y) ± SD (range)	61.2 ± 10.9 (32-83)
Race (%)	
White	93.2
Black	5.9
Other	0.8
Body mass index	26.7 ± 4.7 (18-45)
Smoker (yes/no)	
No	77.6%
Yes	12.2%
No answer	9.7%
Prior continence and/or prolapse surgery	
No	6.3%
Yes	93.7%

Table III. Subsequent surgical procedures after index sacral colpopexy

Type of surgery	*No. of patients (%)*
None	222 (90.6)
TVT	12 (5.8)
Repeat prolapse operation	4 (1.9)
Removal of eroded graft	5 (2.4)
Fascia lata sling	1 (0.5)
Urethrolysis	1 (0.5)
Total	245 (100)

examinations as previously described.[9] Pelvic organ prolapse was assessed according to the International Continence Society's POP-Q system. All patients underwent prolapse assessment in both the supine and standing position while performing a maximum Valsalva maneuver. All patients also underwent multichannel urodynamic studies with concomitant support of their prolapse, including retrograde cystometry, urethral pressure profilometry, cough and Valsalva leak point pressure assessment, voiding pressure studies, uroflowometry, and postvoid residual assessment. Methods, definitions, and descriptions conform to the standards recommended by the International Continence Society.[10] Our standard postoperative follow-up included office visits and POP-Q assessment at 6 weeks, 3 months, 6 months, and yearly thereafter. Charts were reviewed to identify demographics, history, intraoperative, and postoperative events.

POP-Q staging and POP-Q point positions were followed over time as our objective endpoint of interest. Objective failure was defined as POP-Q stage II or greater at any postoperative interval. We controlled for selection bias by comparing responders to nonresponders for preoperative clinical and demographic data, as well as postoperative subjective outcome measures. Responders were defined as those patients who were available for postoperative POP-Q staging at a given postoperative interval. Nonresponders were defined as those patients who were scheduled but not available for postoperative POP-Q staging at a given postoperative visit. A validated prolapse specific quality of life instrument[11] was administered by a telephone survey as our postoperative subjective outcome measure. The University of Louisville Human Studies Committee approved the telephone survey protocol. The

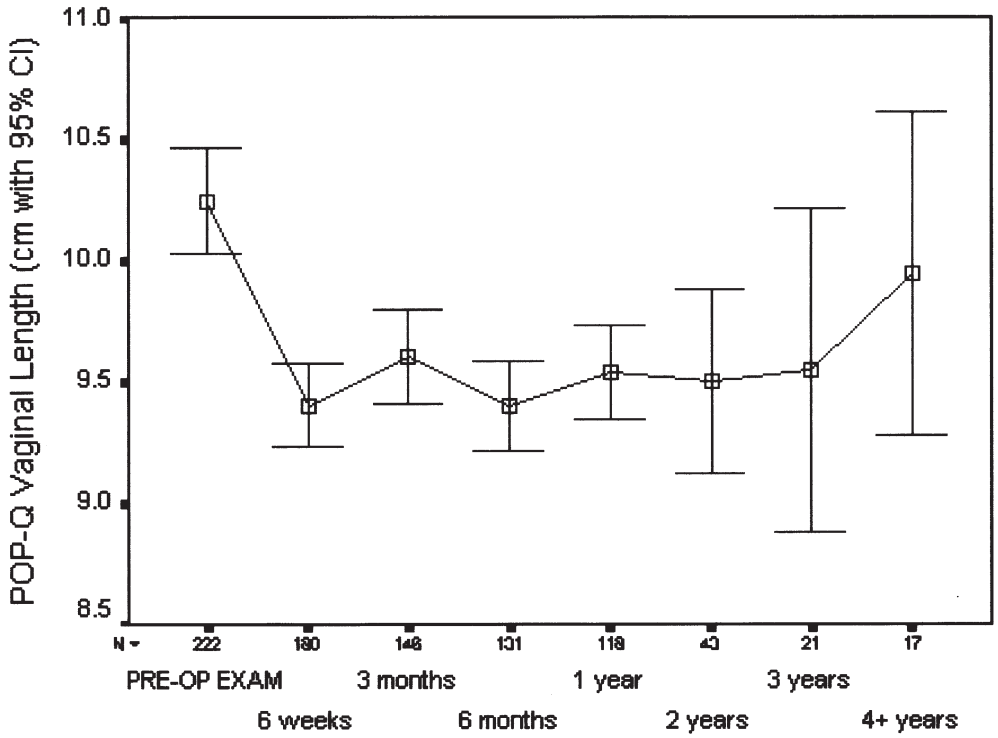

Fig 2. Preoperative and postoperative vaginal length.

Table IV. Proportion of patients with POP-Q measurements available at various follow-up intervals

Interval	*No. of patients for whom follow-up was possible**	*Proportion of patients with POP-Q values*
6 wk	245	182/245 (81.6%)
3 mo	245	147/245 (60.9%)
6 mo	245	133/245 (59.6%)
1 y	228	118/228 (52.9%)
2 y	182	44/182 (24.2%)
3 y	122	21/122 (17.2%)
≥4 y	76	17/76 (22.4%)

*The patients for whom these measurements were impossible had not reached the postoperative interval.

validated quality of life (QOL) instrument contained 15 questions with five Likert scale options ranging from "never" to "all of the time" that are scored from 0 to 4 (Table I). The first 11 questions make up a prolapse specific symptom inventory (PSI), questions 12 to 15 determine QOL score related to those symptoms. Total PSI or QOL scores were calculated by adding the scores for the questions in those sections. Each of the telephone interviews was conducted by one of two independent examiners with no prior relationships to any of the study patients.

We also collected postoperative complications such as erosion of the synthetic mesh through the vaginal wall. Because all mesh erosions are handled in the operating room, the patient charts were compared with our surgical schedule logs to make sure all cases of vaginal mesh erosion were identified. Charts were also reviewed to identify patients who required prolapse or incontinence surgery after the index colpopexy.

Statistical analysis. POP-Q staging and POP-Q point positions were followed over time because of the time-dependent effectiveness of prolapse surgery reported in the medical literature.[12] Life-table analysis that used Kaplan-Meier statistics were not chosen because they require strict end points (mortality for example). We chose a nonparametric repeated measures analysis (Wilcoxon test) because the exact date of surgical failure is unattainable in most cases. The POP-Q stage and POP-Q point positions at each postoperative visit were compared with preoperative values for this analysis. Mean POP-Q point positions and 95% CIs were calculated to establish the accuracy and magnitude of these differences.

We compared responders with nonresponders for clinical, demographic, and subjective outcome measures with

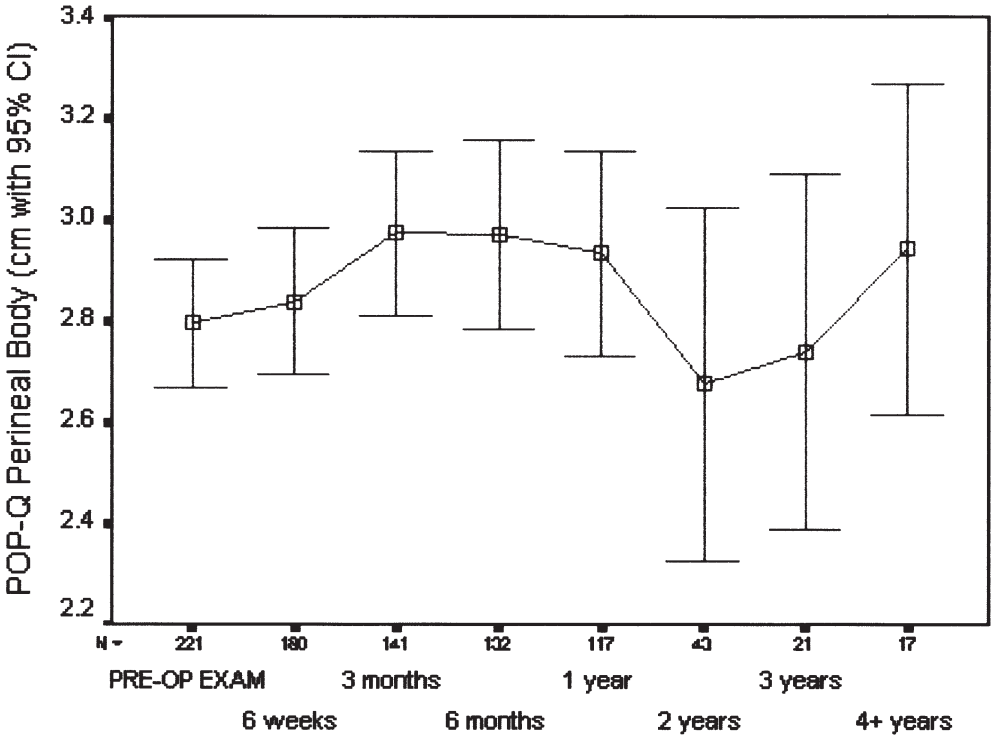

Fig 3. Preoperative and postoperative perineal body measurements *(PB)*.

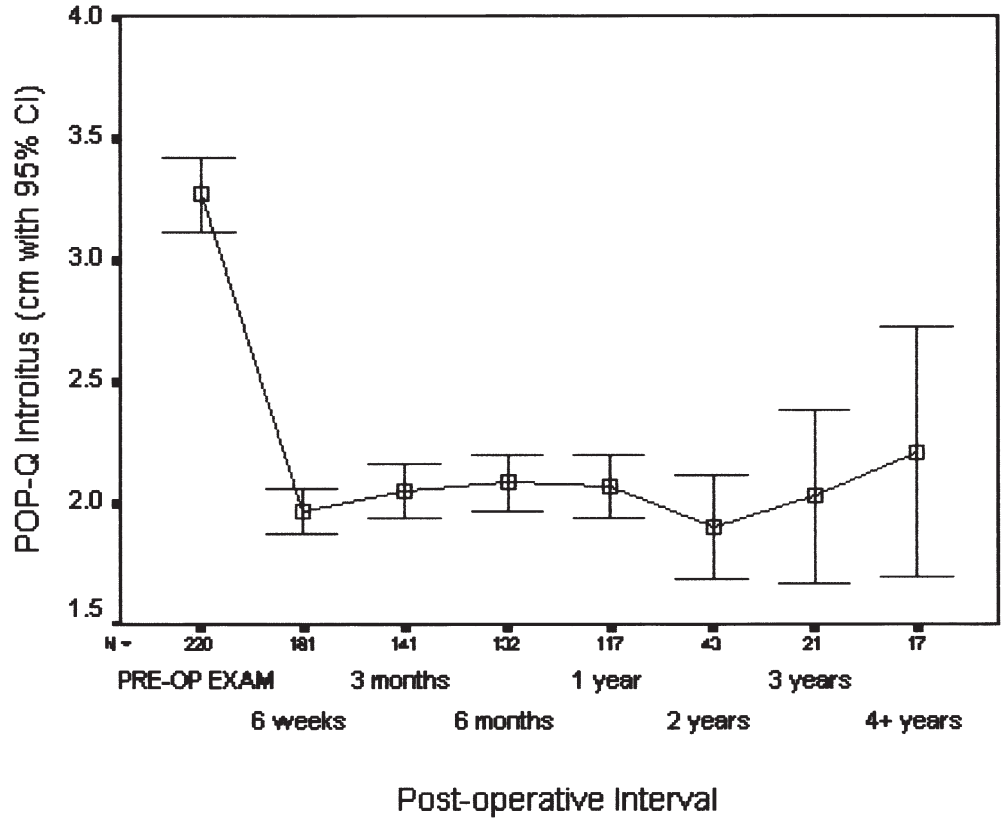

Fig 4. Preoperative and postoperative genital hiatus (introitus).

Table V. Comparison of groups with and without postoperative POP-Q values at various postoperative intervals for objective measures

Postoperative interval	*POP-Q data?**	*Mean age ± SD (y)*	*Mean BMI ± SD*	*Mean EBL ± SD*	*Mean preoperative POP-Q score*
6 wk	Yes (n = 182)	61 ± 11	26 ± 4	337 ± 213	2.6 ± 0.6
		(*P* = .73)	(*P* = .068)	(*P* = .13)	(*P* = .78)
	No (n = 36)	62 ± 11	28 ± 5	304 ± 172	2.5 ± 0.6
3 mo	Yes (n = 147)	62 ± 10	27 ± 5	333 ± 203	2.6 ± 0.6
		(*P* = .71)	(*P* = .45)	(*P* = .67)	(*P* = .82)
	No (n = 76)	61 ± 12	27 ± 4	321 ± 206	2.5 ± 0.6
6 mo	Yes (n = 133)	63 ± 10	26 ± 4	327 ± 201	2.6 ± 0.6
		(*P* = .006)	(*P* = .39)	(*P* = .78)	(*P* = .74)
	No (n = 90)	59 ± 11	27 ± 4	330 ± 208	2.6 ± 0.5
1 y	Yes (n = 118)	63 ± 10	26 ± 4	326 ± 202	2.5 ± 0.6
		(*P* = .03)	(*P* = .30)	(*P* = .62)	(*P* = .80)
	No (n = 105)	60 ± 12	28 ± 5	340 ± 212	2.6 ± 0.6
2 y	Yes (n = 44)	63 ± 10	25 ± 4	336 ± 214	2.5 ± 0.6
		(*P* = .43)	(*P* = .046)	(*P* = .44)	(*P* = .98)
	No (n = 138)	60 ± 22	28 ± 5	340 ± 211	2.6 ± 0.6
3 y	Yes (n = 44)	64 ± 9	26 ± 6	345 ± 242	2.5 ± 0.8
		(*P* = .06)	(*P* = .43)	(*P* = .14)	(*P* = .81)
	No (n = 10)	58 ± 12	27 ± 5	356 ± 203	2.5 ± 0.5
≥4 y	Yes (n = 17)	60 ± 10	25 ± 4	431 ± 234	2.6 ± 0.6
		(*P* = .68)	(*P* = .92)	(*P* = .17)	(*P* = .70)
	No (n = 59)	57 ± 11	26 ± 5	332 ± 211	2.6 ± 0.5

*Yes = Patient returned for POP-Q examination at a given postoperative interval; No = patient failed to return for examination.
†Yes = Patient had prolapse or incontinence surgery before index colpopexy; No = no prior prolapse or incontinence surgery.
BMI, Body mass index; *EBL,* estimated blood loss; *AA,* African American; *W,* white; *O,* other.

Student *t* tests for parametric continuous variables, Mann-Whitney tests for nonparametric continuous variables, and χ^2 tests for association or Fisher exact tests for categorical variables where appropriate. *P* values of less than .05 were considered significant.

Results

During the study period, 245 patients underwent abdominal sacral colpopexy with synthetic mesh through the Division of Urogynecology and Reconstructive Pelvic Surgery. There were 22 patients for whom no preoperative POP-Q measures could be found. We kept these patients in the study group because we had postoperative clinical and demographic information about them. Demographics of the study group are provided in Table II.

In addition to sacral colpopexy, the study group received 11 hysterectomies, 145 paravaginal repairs, 39 posterior repairs, 106 Burch procedures, 48 tension-free vaginal tape procedures, 17 suburethral slings using donor fascia lata, 22 perineorraphies, 47 Halban procedures, and 6 anterior colporraphies. The mean estimated blood loss per patient was 328.5 ± 203.4 mL (range, 50-1300) and two patients required blood transfusions. Intraoperative complications included one cystotomy repaired without sequela and two patients with ureteral obstructions noted and relieved during surgery. Immediate postoperative complications included two small bowel obstructions requiring reoperation, one femoral neuropathy that spontaneously resolved over 3 months, one fascial dehiscence, two deep venous thromboses, and one pulmonary embolism.

Table III lists the 23 patients who underwent a repair of graft erosion, a prolapse operation, or a continence operation after the index colpopexy. Six patients (2.4%) had postoperative graft erosion through the vaginal wall. Of the 11 patients who underwent a hysterectomy at the time of their colpopexy, 3 (27.3%) had erosion of graft material, but of the 234 patients who did not have a hysterectomy at the time of their colpopexy, 3 (1.3%) mesh erosions occurred. This difference in mesh erosion rates between the hysterectomy and nonhysterectomy groups was significant ($P < .001$).

Fig 1 shows the preoperative and postoperative POP-Q stages in graphic form with 95% CIs. The graphs for all apical, anterior, and posterior POP-Q points at all postoperative intervals looked very similar to this POP-Q stage graph and were therefore omitted from this report. There were statistically significant improvements in POP-Q stage and all POP-Q data points, except total vaginal length and perineal body measures at all postoperative intervals (*P* values between .00001 and .012 for all). There were statistically significant differences between preoperative and postoperative vaginal length until the ≥4-year postoperative interval (Fig 2). Perineal body measurements did not change significantly (Fig 3). Introitus measurements were significantly smaller at all postoperative intervals (Fig 4).

Objective failure was defined as any postoperative POP-Q point ≥ stage II. Such failure was found in 37 (15.1%)

Prior surgery?†	*Race (%)*	*Smoker?*
Yes 95%, no 5%	AA 5.1, W 94.4, O –0.6	Yes 13%, no 76%, don't know 11%
(*P* = .65)	(*P* = .44)	(*P* = .48)
Yes 90%, no 10%	AA 8.5, W 89.8, O 0.4	Yes 10%, no 83%, don't know 7%
Yes 93%, no 7%	AA 7.7, W 91.5, O 0.8	Yes 9%, no 83% don't know 8%
(*P* = .49)	(*P* = .32)	(*P* = .04)
Yes 95%, no 5%	AA 3.2, W 95.8, O 1.0	Yes 18%, no 70%, don't know 12%
Yes 92%, no 8%	AA 6.9, W 93.1, O 0	Yes 12%, no 77%, don't know 11%
(*P* = .43)	(*P* = .87)	(*P* = .51)
Yes 95%, no 5%	AA 4.5, W 94.6, O 0.9	Yes 9%, no 83%, don't know 8%
Yes 96%, no 4%	AA 5.1, W 94.4, O 0.6	Yes 10%, no 83%, don't know 7%
(*P* = .19)	(*P* = .45)	(*P* = .36)
Yes 91%, no 9%	AA 8.5, W 89.9, O 0.4	Yes 13%, no 76%, don't know 11%
Yes 92%, no 8%	AA 2.3, W 97.7, O 0	Yes 5%, no 84%, don't know 11%
(*P* = .45)	(*P* = .54)	(*P* = .20)
Yes 89%, no 11%	AA 5, W 94.3, O 0.7	Yes 14%, no 77%, don't know 9%
Yes 93%, no 7%	AA 5, W 95, O 0	Yes 5%, no 85%, don't know 10%
(*P* = .49)	(*P* = .64)	(*P* = 0.38)
Yes 95%, no 5%	AA 1.9, W 97.1, O 1	Yes 14%, no 72%, don't know 14%
Yes 88%, no 12%	AA 6.9, W 93.1, O 0	Yes 0%, no 88%, don't know 12%
(*P* = .87)	(*P* = .88)	(*P* = .07)
Yes 85%, no 15%	AA 4.5, W 94.5, O 0.9	Yes 16%, no 71%, don't know 13%

Table VI. Comparison of groups with and without postoperative POP-Q values at various postoperative intervals for subjective measures

Postoperative interval	*POP-Q data?*	*PSI score**	*QOL score†*
6 wk	Yes (n = 158)	6.1 ± 4.9 (*P* = .76)	0.84 ± 2.3 (*P* = .68)
	No (n = 48)	5.8 ± 4.8	0.67 ± 1.9
3 mo	Yes (n = 132)	5.6 ± 4.5 (*P* = .1)	0.69 ± 2.1 (*P* = .29)
	No (n = 74)	6.8 ± 5.4	0.97 ± 2.4
6 mo	Yes (n = 119)	5.3 ± 4.2 (*P* = .045)	0.52 ± 1.7 (*P* = .62)
	No (n = 87)	7.0 ± 5.6	1.2 ± 2.7
1 y	Yes (n = 106)	5.3 ± 3.9 (*P* = .19)	0.55 ± 1.8 (*P* = .14)
	No (n = 91)	6.7 ± 5.5	1.0 ± 2.5
2 y	Yes (n = 42)	4.5 ± 3.3 (*P* = .05)	0.60 ± 2.3 (*P* = .21)
	No (n = 116)	6.3 ± 4.6	0.72 ± 2.1
3 y	Yes (n = 20)	4.5 ± 3.5 (*P* = .21)	0.2 ± 0.89 (*P* = .35)
	No (n = 81)	6.1 ± 4.8	0.5 ± 1.9≥
4 y	Yes (n = 14)	5.3 ± 3.9 (*P* = .99)	0.6 ± 2.1 (*P* = .69)
	No (n = 44)	5.7 ± 5.1	0.5 ± 1.9

*PSI score = Sum of score of questions 1 to 11 (Table I).
†QOL score = Sum of score of questions 12 to 15 (Table I).

patients. Of these, 26 (70.3%) occurred within 6 months, and 30 (81.1%) were discovered during the first postoperative year. Another 5 objective failures were discovered between 12 and 24 months after surgery, so 94.6% of objective failures occurred within the first 24 months after surgery. Of the objective failures, 22 (57.9%) were of the anterior segment, 14 (36.8%) were of the posterior compartment, and 2 (5.3%) were combinations of the two. No apical failures were observed.

The proportion of patients who returned to the office for scheduled visits decreased with increasing postoperative intervals as expected (Table IV). At each postoperative interval, those patients with postoperative POP-Q data points (responders) and those without (nonresponders) were compared for objective and subjective differences. Table V summarizes the comparisons of objective data for responders and nonresponders. There were rare statistical differences between clinical and demographic characteristics of these groups. At 3 months, there were more smokers in the nonresponder group (18% vs 9%, *P* = .04). At 6 months, the responders were older (63 years vs 59 years, *P* = .006) than the nonresponders. A similar age dis-

crepancy was found at 1 year (responders = 63 years, nonresponders = 60 years, $P = .03$). At 2 years, body mass index was higher for the nonresponders (28 vs 25, $P = .046$).

Our subjective assessments were collected via telephone interviews. A total of 206 patients (84.1% of the study population) were contacted by telephone between September and November 2001. The mean time between a patient's index sacral colpopexy and her telephone interview was 3.3 years (range, 0.8-6.9 years). All the patients contacted agreed to complete the validated PSI and QOL scale. Table VI summarizes the PSI and QOL scores for responders and nonresponders at all postoperative intervals. The only statistically significant difference was found at 6 months, when the PSI score was worse for responders than nonresponders (5.3 vs 7.0, $P = .045$).

Comment

To the best of our knowledge, this is the largest reported case series of abdominal sacral colpopexy procedures performed with synthetic mesh by using the POP-Q system as the objective outcome measure. Our data confirms several points from previous studies, namely, that sacral colpopexies are quite effective, that concomitant hysterectomy predisposes a patient to vaginal mesh erosion,[13,14] and that objective failures predominantly involve the anterior compartment.

Attrition threatens the validity of even the most rigorous study design, the randomized clinical trial. However, randomization should control for selection bias as long as attrition rates do not differ in the study groups. In nonrandomized case series such as ours, selection bias threatens validity because healthier patients are more likely to keep their return appointments and thus have more complete data sets. This "healthy volunteer effect" explains the better outcomes reported in case series than seen in clinical practice. It is incumbent on researchers to control for selection bias when presenting outcome data in nonrandomized case series through statistical methods. We did so by comparing responders to nonresponders for objective and subjective measures, and there were no clinically significant differences between the two groups. Therefore, despite the postoperative attrition, we have no reason to question our conclusion that the vast majority of objective surgical failures (POP-Q stage ≥ II) after sacral colpopexy occur within the first 2 postoperative years. In other words, no selection bias or "healthy volunteer effect" seems to have affected this study.

For our POP-Q data point analysis, we chose a nonparametric repeated measures analysis (Wilcoxon test) because the exact date of surgical failure is unattainable in most cases. We believe that this statistical approach is more valid than life-table analysis using Kaplan Meier statistics.

Despite our attempts to control for selection bias, our study has several limitations. Ideally, POP-Q data points would have been assessed before and after surgery by an independent examiner (ie, not the patient's surgeon). This was not the case for our study. Also, the validated survey we used to assess subjective outcomes has not yet been correlated to degree of pelvic organ prolapse. Nevertheless, it was reassuring to find relatively low PSI and QOL scores (suggesting satisfaction) for the patients with and without objective follow-up because the fundamental goal of pelvic reconstructive surgery is to improve patients' quality of life. We look forward to the development of prolapse specific QOL instruments that are both externally and internally validated.

Our findings suggest that future prospective studies involving sacral colpopexy may be designed with only 1 or 2 years of follow-up, without significantly compromising their validity.

REFERENCES

1. Toozs-Hobson P, Boos K, Cardozo L. Management of vaginal vault prolapse. Br J Obstet Gynaecol 1998;105:13-7.
2. Benson JT, Lucente V, McClellan E. Vaginal versus abdominal reconstructive surgery for the treatment of pelvic support defects: a prospective randomized study with long-term outcome evaluation. Am J Obstet Gynecol 1996;175:1418-22.
3. Timmons MC, Addison WA, Addison SB, Cavenar MG. Abdominal sacral colpopexy in 163 women with posthysterectomy vaginal vault prolapse and enterocele: evolution of operative techniques. J Reprod Med 1992;37:323-7.
4. Hardiman PJ, Drutz HP. Sacrospinous vault suspension and abdominal colposacropexy: success rates and complications. Am J Obstet Gynecol 1996;175:612-6.
5. Bump RC, Mattiasson A, Bo K, Brubaker LP, DeLancey JO, Klarskov P, et al. The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. Am J Obstet Gynecol 1996;175:10-7.
6. Weber AM, Abrams P, Brubaker L, Cundiff G, Davis G, Dmochowski RR, et al. The standardization of terminology for researchers in female pelvic floor disorders. Int Urogynecol J 2001;12:178-86.
7. Shull BL, Bachofen C, Coates KW, Kuehl TJ. A transvaginal approach to repair of apical and other associated sites of pelvic organ prolapse with uterosacral ligaments. Am J Obstet Gynecol 2000;183:1365-74.
8. Shull BL, Capen CV, Riggs MW, Kuehl TJ. Preoperative and postoperative analysis of site-specific pelvic support defects in 81 women treated with sacrospinous ligament suspension and pelvic reconstruction. Am J Obstet Gynecol 1992;166:1764-71.
9. Heit MH. Preoperative evaluation of recurrent urogynecology and reconstructive pelvic surgery disorders. In: Gershenson DM, DeCherney AH, Curry SL, et al, editors. Operative gynecology. 2nd ed. Philadelphia: WB Saunders; 2001. p. 449-60.
10. Abrams P, Blavias JG, Stanton SL, Andersen JT. The standardization of terminology of lower urinary tract function: the International Continence Society Committee on Standardization of Terminology. Scand J Urol Nephrol Suppl 1988;114:5-19.
11. Kobashi KC, Gormley EA, Govier F, Hadley R, Luber K, Nitti V, et al. Development of a validated quality of life assessment instrument for patients with pelvic prolapse: proceedings of the American Urological Association 95th Annual Meeting. J Urol 2000;163:76.
12. Barber MB, Visco AG, Weidner AC, Amundsen CL. Bilateral uterosacral ligament vaginal vault suspension with site specific endopelvic fascia defect repair for treatment of pelvic organ prolapse. Am J Obstet Gynecol 2000;183:1402-11.
13. Kohli N, Walsh PM, Roat TW, Karram MM. Mesh erosion after abdominal sacrocolpopexy. Obstet Gynecol 1998;92:999-1004.
14. Visco AG, Weidner AC, Barber MD, Myers ER, Cundiff GW, Bump RC, et al. Vaginal mesh erosion after abdominal sacral colpopexy. Am J Obstet Gynecol 2001;184:297-302.

Discussion

Dr Deborah Myers, Providence, RI. The paper entitled "Long-term success of abdominal sacral colpopexy using synthetic mesh" provides a retrospective review with 245 patients, a large number, with a mean follow-up of 3 years. The retrospective nature of the paper does provide a first step to help determine the length of study period required for prospective trials involving sacral colpopexy. It is probably one of the largest series that uses the POP-Q system in following abdominal sacral colpopexy, but the authors should not claim priority without documentation of a literature search. The authors should also be commended for looking at postoperative subjective outcomes, which are so needed in our literature on surgical outcomes.

The authors retrospectively analyzed 245 patients who underwent abdominal sacral colpopexy and other concomitant reconstructive procedures. They observed at what point in time, between 6 weeks and more than 4 years, that failure occurred. The authors had patients from 0.8 to 6.9 years for follow-up, with a mean follow-up time of 3.3 years. The authors found 37 failures, for a failure rate of 15%, with 94.6% of these failures occurring within the first 2 years. A recurrence rate of 15%, however, is not "rare" as the authors' state in their condensation. The authors set up their definition of failure as any stage II prolapse whether it is of the anterior wall, posterior wall, or apex. The authors did not report any apical failures. The failures seen after surgery were primarily of the anterior wall. Thus, the primary aim of the paper, which is "to determine the minimum meaningful study period required for prospective trials involving sacral colpopexy," could not be answered. Thus, their conclusion that "it is reasonable to construct randomized controlled trials involving sacral colpopexy that only include 1- or 2-year follow-up" cannot be made. Perhaps a better aim for the paper would be to determine the period during which failure of reconstructive pelvic surgery is most likely to occur.

In addition, the mean duration of follow-up was only 3.3 years. The conclusion that only 2 years of follow-up is valid could only be made if patients had been monitored for 5 to 10 years. The authors would need to demonstrate that no other significant events such as prolapse, erosion, or new onset of urinary incontinence occurred during a 5- to 10-year period. Thus, the only valid conclusion that can be drawn from the paper is that the rate of recurrence of prolapse was 15% within 2 years of surgery. The authors' conclusion is especially not valid because they noted only a 15% recurrence rate. How can the reader assume that the other 85%, who did not recur within the 2-year period, did not recur at 7 or 10 years?

In Table IV, the authors report a sharp decline in their follow-up rate after 2 years. How does the reader know if those women not available for follow-up had recurrence and simply went elsewhere? The authors conclude that responders and the nonresponders were similar groups. The authors in their paper explain that to control for bias, the preoperative clinical and demographic data of the responders to the nonresponders were compared, as well as the postoperative subjective outcome data. However, the authors compared these 2 groups with preoperative indices such as BMI, age, and smoking. These indices are weak risk factors for recurrence of prolapse. Unfortunately, no clear risk factors, ie, strong predictors, for recurrence of prolapse have been established. Hence, the authors' conclusion that the success or failure rate in the 2 groups is similar cannot be made.

The information about the statistically higher rate of mesh erosion that occurred in patients with hysterectomy versus those without hysterectomy is clinically important and should be emphasized in the discussion. Complications such as mesh erosion may occur only after several years. The authors need to make a statement to the effect that despite the success of abdominal sacral colpopexy with synthetic mesh in treating apical prolapse, patients should be followed-up long-term for possible mesh erosion.

The authors describe the weaknesses in their study: the high lost to follow-up rate, the potential bias inherent when the postoperative examination was not performed by an independent examiner, and also that the validated survey used to assess subjective outcomes has not been correlated to the degree of prolapse. Perhaps, the authors could reanalyze their postoperative POPQ data with the subjective outcome data as another useful aspect of this paper. The authors themselves state that this retrospective review serves as a template on which a prospective trial can be developed and they have accomplished that task. This paper has significance in that it provides a large amount of information with POP-Q analysis about abdominal sacral colpopexy and pelvic reconstructive surgery that is key in developing future trials.

Dr Culligan (Closing). I will attempt to deal with the issues you raised in order.

We performed a MEDLINE search including years 1966 to January 2002. We then performed an Index Medicus search back to 1900. Finally, we reviewed all the referenced articles in the citations generated by our searches. After doing all of that, we realized that our study is the largest sacral colopexy series using objective and subjective endpoints. Few studies have used POP-Q data points as the objective endpoint, and no other studies have used the Wilcoxon test for analysis. We believe this test is the best way to analyze POP-Q points for the reasons I mentioned in my presentation.

I disagree with your contention that our length of follow-up is not adequate to support our conclusions. Going into this project, we expected a significant attrition rate. Most surgical studies have significant loss to follow-up over the long term. Our study is not unique in that respect, but our manner of dealing with this attrition is

unique. As you stated, at each postoperative interval we compared those women with objective follow-up with those without objective follow-up to estimate the effects of selection bias. I agree that there are no established demographic risk factors for prolapse recurrence, but that does not mean such factors do not exist. Because there is limited information about sacral colpopexy failure, we could not possibly know risk factors for failure. So we were forced to analyze plausible demographic factors, which is what we did.

We then took this analysis a step further by contacting 85% of the total study group to assess their prolapse symptoms and quality of life. We cannot, as you suggested, correlate patients' subjective assessments with this POP-Q stage because the questionnaire was administered over the telephone. In other words, the POP-Q assessment was not carried out at the same time as the symptom questionnaire. The point of contacting all these women was to get an idea whether we had a large cohort of symptomatic failures out there who had not returned to our office. We are satisfied that no such cohort exists.

The subjective assessment tool we used has not been validated against the POP-Q, which I think brings up an interesting point. After prolapse surgery, do women care more about their symptoms or their POP-Q score? Who is to say that the POP-Q should not be validated against the symptom assessment tool we used?

Obviously, it would be ideal to have a complete set of 5- to 10-year subjective and objective follow-up for any study regarding prolapse surgery. Our conclusions do not contradict that fact. We are simply suggesting that 5 to 10 years of follow-up is not necessary to draw valid conclusions in future randomized clinical trials involving prolapse surgery. We hope these findings will prompt more researchers to carry out randomized clinical trials involving prolapse surgery.