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Long-Term Outcomes of Robotic-Assisted Laparoscopic Sacrocolpopexy Using Lightweight Y-Mesh

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Objective: The objective of this study was to describe anatomic and symptomatic outcomes at 5 years or longer after robotic-assisted laparoscopic sacrocolpopexy using very lightweight polypropylene Y-mesh.

Methods: A prospective analysis of consecutive patients who underwent surgery at a single center between 2007 and 2011 was performed. Patients consented to objective and subjective assessment at 5 years or longer postoperatively. Surgical success was defined as meeting all of the following: (1) no retreatment for pelvic organ prolapse (POP) since surgery, (2) no prolapse beyond the introitus, (3) no apical descent below -5, and (4) no prolapse symptoms reported. Secondary outcome measures included Sandvik Incontinence Severity Index, the PFDI-20, the PFIQ-7, the PISQ-12, and the SSQ-8, rates of dyspareunia, mesh complications, and subjects' need for any surgical or nonsurgical prolapse treatment since their index surgery.

Results: Eighty percent of the potential study group (253/316) presented for examination and subjective assessment at 5 years or longer after their index surgeries.

The surgical success rate was 226 (89.3%) of 253 with no apical failures. Only 4.4% (11/253) of the group met both objective and subjective failure criteria. Sixteen patients were classified as *surgical failure* owing to subjective criteria alone despite having no significant objective prolapse on examination. Ten patients (4%) elected to undergo subsequent POP repair. These operations consisted of 5 native tissue anterior repairs and 5 native tissue posterior repairs. In addition, 1 patient elected to use a pessary for recurrent anterior POP. The remaining 16 patients who experienced surgical failure elected no further prolapse treatment.

Conclusions: Robotic-assisted laparoscopic sacrocolpopexy using very lightweight mesh provided excellent long-term results with no mesh-related complications.

Key Words: robotic sacrocolpopexy, pelvic organ prolapse

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Pelvic organ prolapse (POP) is a common debilitating condition in which the female pelvic organs protrude into the vagina creating discomfort as well as bladder, bowel, and sexual dysfunction. These disorders result in approximately 300,000 reconstructive surgeries per year in the United States alone.¹ As the United States elderly population grows, the number of women with POP is expected to increase another 50% by 2050.² Sacrocolpopexy, which is considered the most durable operation

for advanced POP and serves as the criterion standard against which other operations are compared,³ involves attachment of one end of a graft material (usually polypropylene mesh) to the anterior and posterior vaginal walls and fixation of the other end to the anterior longitudinal ligament of the sacrum (Fig. 1). Despite its acceptance as the most definitive surgery to correct POP, a recent long-term follow-up study reported disappointing rates of success and mesh complications 5 to 7 years postoperatively.⁴ However, the relevance of those findings may be limited by the open abdominal surgical approach and older generation heavier graft materials used for the sacrocolpopexies in that trial. Currently, most sacrocolpopexies are performed laparoscopically (with or without robotic assistance) using very lightweight monofilament polypropylene mesh. For example, 2 studies of robotic-assisted laparoscopic sacrocolpopexy performed with very lightweight Y-mesh demonstrated high surgical success rates and no mesh exposures or mesh-related complications at greater than or equal to 12 months.^{5,6} These results suggest that a more up to date version of sacrocolpopexy (as compared with the open abdominal surgeries mentioned previously) might demonstrate better rates of long-term success and more acceptable rates of mesh complications. Therefore, our objective was to establish long-term cure and complication rates after robotic-assisted laparoscopic sacrocolpopexy using lightweight polypropylene Y-mesh products.

MATERIALS AND METHODS

This was a single-center cohort study approved by the Atlantic Health System Institutional Review Board (R-599819-2) and listed on www.clinicaltrials.gov (NCT02248935). The potential study group included patients who, after a thorough preoperative informed consent process, had chosen to undergo robotic-assisted laparoscopic sacrocolpopexy as treatment for their symptomatic stage II or greater apical POP. All patients who underwent robotic-assisted laparoscopic sacrocolpopexy between 2007 and 2011 made up our potential study group.

Our study interval was chosen to allow at least 5-year objective and subjective follow-up for all study subjects. Study participation was offered via letter and/or telephone, and each subject went through a new informed consent process specific to this study before long-term data collection. Patients were excluded if they refused to participate or were lost to follow-up. Patients were considered lost to follow-up when we could not determine current contact information or when they did not respond to our letter and at least 3 follow-up phone calls. Only patients with complete sets of preoperative and postoperative objective and subjective data were included in our long-term outcome determinations. To understand any potential effects of selection bias, participants were compared with nonparticipants for demographics, perioperative variables, and outcome measures at last follow-up visit.

Study subjects' demographic information was recorded including age, body mass index (BMI), ethnicity, history of prior prolapse or incontinence surgery and/or prior hysterectomy, smoking status, and menopausal status. Preoperative evaluations included detailed urogynecologic history and physical examination. Objective degree of POP was measured via the pelvic organ prolapse quantification (POP-Q) system.⁷ Preoperative subjective

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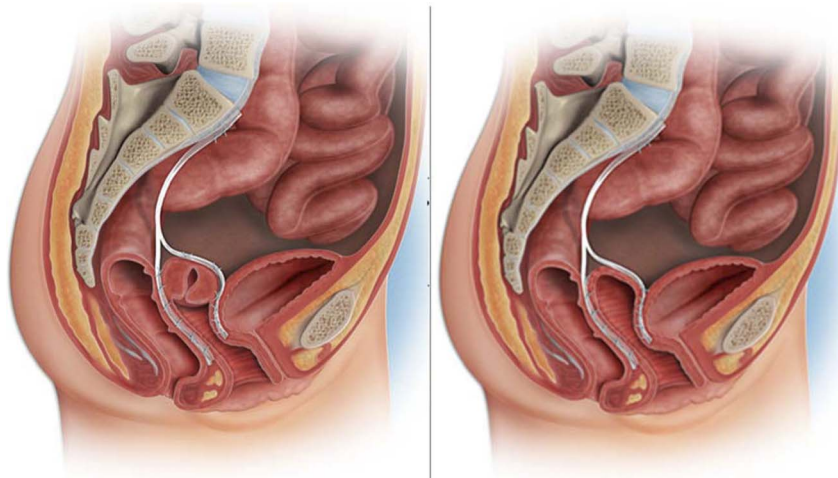


FIGURE 1. Desired surgical outcomes of a robotic-assisted laparoscopic sacrocolpopexy with and without the cervix in place.

assessment included the Sandvik Incontinence Severity Index,⁸ the Pelvic Floor Distress Inventory—Short Form 20 (PFDI-20),⁹ the Pelvic Floor Impact Questionnaire—Short Form 7 (PFIQ-7),⁹ the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire 12 (PISQ-12).¹⁰ Each of the aforementioned variables plus the Surgical Satisfaction Questionnaire 8 (SSQ-8)¹¹ were collected again at 5 years or longer postoperatively. In addition at the 5-year or longer follow-up visit, we recorded rates of dyspareunia, mesh complications, and subjects' need for any surgical or nonsurgical prolapse treatment since their index surgery. In addition, subjects were asked whether they had received any treatments for mesh-related complications such as exposures, erosions, or mesh-related pain elsewhere at any point during the postoperative interval.

We categorized patients as *surgical failure* when any of the following criteria were met: (1) POP-Q point C of greater than or equal to -5 ; (2) POP-Q points Aa, Ba, Ap, or Bp greater than 0 (ie, beyond the hymen); (3) bothersome bulge symptoms reported by the participant in response to the PFDI-20 questions, "Do you usually have a sensation of bulging or protrusion from the vaginal area?" or "Do you usually have a bulge or something falling out that you can see or feel in the vaginal area?"; or (4) POP surgery or pessary use for prolapse at any point after her index surgery.

All long-term data were collected by female pelvic medicine and reconstructive pelvic surgery fellows who had not been involved in the original surgical procedures. During each postoperative vaginal examination, the examiner attempted to visualize and palpate mesh through the vaginal epithelium. Mesh exposure was defined as any palpable or visible mesh noticed on vaginal examination. Perioperative data were collected including concomitant operations, operative time (defined as time elapsed between trocar insertion and trocar removal), estimated blood loss, length of hospital stay, hospital readmissions, blood transfusions, conversions to laparotomy, and any other intraoperative or postoperative adverse events. Secondary endpoints included SSQ-8 scores, rates of mesh exposure and de novo dyspareunia, and scores of the PFDI-20, PFIQ-7, and SSI. Among participants who were engaging in penetrative intercourse both before and after surgery, we defined de novo dyspareunia using question 5 of the PISQ-12, which asks "Do you feel pain during sexual intercourse?" We defined dyspareunia as an answer of 2 or greater ("sometimes") and de novo dyspareunia as a score of 2 or greater among patients who reported lower preoperative scores. Mesh exposure was defined as any visible or palpable mesh at any point during the postoperative period.

All surgeries were performed via a previously reported standardized technique.^{5,6} Briefly, supracervical hysterectomies were performed when uteri were present. The vesicovaginal dissections were carried down to the level of the trigone, and the rectovaginal dissections were carried to the level of the perineum (Fig. 1). The polypropylene Y-shaped mesh (either Restorelle Y-mesh [Coloplast, Humlebæk, Denmark] or Alyte Y-mesh graft [C.R. Bard, Covington, GA]) was tailored to each patient's defect and attached to the vagina using interrupted polytetrafluoroethylene sutures (CV4 Gore-Tex suture on TH-26 needles; Gore Medical Products Division, Flagstaff, AZ). Typically, the posterior mesh arms were between 9 and 11 cm in length, and the anterior arms were between 5 and 7 cm in length. No vaginal manipulation was performed for cases involving supracervical hysterectomy, as all uterine and cervical traction was performed via the robotic single-toothed tenaculum (Intuitive Surgical, Sunnyvale, CA). For posthysterectomy cases, the vaginal dissection and suturing were facilitated by vaginal manipulation with a Breisky retractor (for the posterior space) measuring 160 mm \times 35 mm and the Tapered Vaginal Stent (for the anterior space) (Marina Medical Instruments, Davie, FL). The proximal graft attachments to the anterior longitudinal ligament were performed via zero-gauge polyester sutures (Ethibond on SH needles; Ethicon, Somerville, NJ), and the mesh was buried beneath peritoneum using zero-gauge polyglecaprone sutures (Monocryl on SH needles; Ethicon, Somerville, NJ). Concomitant mesh midurethral slings were offered to patients who demonstrated preoperative stress incontinence with reduction of their prolapse during urodynamic studies. Statistical analyses were performed using SAS 9.2 (SAS, Cary, NC). The primary outcome was analyzed using Wilcoxon signed rank test and paired *t* test. In addition, χ^2 and Fisher exact test were used with the α set to 0.05.

RESULTS

During our study period, 320 patients underwent robotic-assisted laparoscopic sacrocolpopexy. Of those, 4 died before our long-term follow-up owing to causes unrelated to their index surgeries, leaving a potential study group of 316. Of those, 63 refused or were lost to follow-up. Therefore, our long-term study group consisted of 253 women (80% of potential study group) who consented to and presented for objective and subjective assessment at 5 years or longer after their index sacrocolpopexy operations. The mean follow-up period was 66 months with a

TABLE 1. Perioperative Characteristics of the Study Population (N = 316)

Characteristic	Value
Age, y	57.7 (±9.4)
BMI, kg/m ²	26 (±4.1)
Vaginal parity	2.0 (0.0, 7.0)
Sexually active, %	64.5
Current smokers, %	4.1
Prior incontinence surgery, %	9.2
Prior prolapse surgery, %	13.9
Prior hysterectomy, %	24.1
Current systemic HRT, %	8.2
Postmenopausal, %	74.1
Race, %	
White	93.4
Black	1.0
Hispanic	3.5
Asian	0.6
Other	1.5
Mesh type	
Restorelle, %	47.2
Alyte, %	52.8
Operative time	146.54 (±25.9)
Postoperative febrile morbidity, %	0.6
Blood loss, mL	51 (±40.2)
Ileus or bowel obstruction, %	0
Days in hospital	1.00
Concomitant supracervical hysterectomy, %	76.0
Concomitant sling, %	76.9
Concomitant perineorrhaphy, %	17.7
PFDI-20	101.4 (±56.7)
POPDI-6	41.5 (±23.1)
CRADI-8	20.8 (±20.1)
UDI-6	38.4 (±25.2)
PFIQ-7	62.2 (±58.8)
Aa, cm	1.2 (−3.0, 3.0)
Ba, cm	1.7 (−3, 10)
C, cm	−1.0 (−4.0, 10.0)
Genital hiatus, cm	4.1 (±1.6)
Perineal body, cm	2.4 (±0.9)
Total vaginal length, cm	9.5 (±1.0)
Ap, cm	−1.0 (−3.0, 3.0)
Bp, cm	−1.0 (−3.0, 10.0)
POP-Q stage 1	0
POP-Q stage 2	128 (40.5%)
POP-Q stage 3	177 (56%)
POP-Q stage 4	11 (3.5%)

HRT, hormone replacement therapy; POPDI-6, pelvic organ distress inventory - 6; CRADI-8, colorectal anal distress inventory - 8; UDI-6, urinary distress inventory - 6.

range of 58 to 80 months. Table 1 includes the demographic and relevant perioperative information for all 316 patients in our potential study group, and Table 2 includes a comparison of these data between patients with versus those without long-term follow-up. There were no significant differences between these groups. Also, there were no differences found between the

2 mesh products for any variables, so the entire 253 patients were considered as 1 group. All surgeries were completed robotically as planned, with no conversions to laparotomy or to traditional laparoscopy. There were no intraoperative bowel or bladder injuries, and no patients required blood transfusion. Only 1.8% (58/316) of the study group received concomitant vaginal repair, and all of those were perineorrhaphies.

Among the 253 patients who returned at 5 years or longer, the surgical success rate was 89.3% (226/253). There were no apical (point C) failures. Of the 27 patients who were classified as having experienced surgical failure, 11 (4.4%) met both objective and subjective failure criteria. Of those, 6 were found to have anterior POP-Q points (Aa or Ba) greater than 0, and 5 were found to have posterior POP-Q points (Ap or Bp) greater than 0. There were 16 patients classified as surgical failure owing to subjective criteria alone. In other words, those patients gave PFDI-20 responses consistent with POP despite demonstrating normal POP-Q assessments. One patient was classified as surgical failure owing strictly to objective POP-Q measurements despite denying any prolapse symptoms on PFDI-20. A total of 10 patients elected to undergo subsequent POP repair. These operations consisted of 5 native tissue anterior colporrhaphies and 5 native tissue posterior colporrhaphies. In addition, 1 patient elected to use a pessary for recurrent anterior POP. The remaining 16 patients who experienced surgical failure elected no further prolapse treatment.

Table 3 lists the comparison of preoperative versus postoperative objective and subjective outcome measures for patients with 5-year or longer follow-up. There were no mesh exposures or mesh-related complications found, and the independent examiners could not determine location of mesh edges in any patient. In addition, no patients reported any treatments for any mesh-related complications during the postoperative interval. We attribute this lack of mesh-related complications to our employment of supracervical rather than total hysterectomy as well as our great care to avoid full-thickness bites with our vaginal suturing. The PFDI-20, PFIQ-7, Sandvik Incontinence Severity Index, and PISQ-12 scores had all improved significantly at the 5-year or longer point. Overall SSQ-8 scores were very good, with 88% (223/253) of patients indicating that they were “satisfied” or “very satisfied” with the surgery; 87% (220/253) stating that they would definitely “do it all over again” if they had the chance; and 86% (217/253) stating that they “would definitely recommend to a friend.” Table 4 shows a comparison of subjective and objective outcome measures for our study group at 60 months or longer compared with the last recorded values for those variables among those patients who did not return for long-term follow-up.

DISCUSSION

We found excellent objective and subjective long-term outcomes for robotic-assisted laparoscopic sacrocolpopexy using very lightweight polypropylene Y-mesh. The mean improvements in PFDI-20 and PFIQ-7 scores were well above the minimum clinically important difference threshold reported by Barber et al.⁹ Furthermore, we achieved these success rates in the face of no mesh erosions or extrusions. Of course, we do not know whether any mesh-related complications arose among the group lost to follow-up. The surgical techniques we used and the mesh we used were more consistent with current practice patterns than those used in the Nygaard et al⁴ study suggesting that their disappointing long-term surgical success rate may have been related to outdated materials and techniques. Although the high surgical success rates reported for sacrocolpopexy have long been thought to come at the price of significant mesh-related complications,^{12–15} our findings suggest that the opposite may

TABLE 2. Comparison of Clinical Characteristics of Patients With (n = 253) and Without (n = 63) Follow-up at 60 Months or Longer

Characteristic	≥60 mo Follow-up	No Follow-up at ≥60 mo	P
Age, y	58.2	55.8	0.074
BMI, kg/m ²	25.9	26.0	0.93
Vaginal parity	2.0	2.0	0.32
Sexually active, %	65.3	61.0	0.54
Current smokers, %	3.5	6.5	0.30
Prior incontinence surgery, %	9.8	6.5	0.41
Prior prolapse surgery, %	15.8	6.5	0.02
Prior hysterectomy, %	25.6	17.7	0.20
Current systemic HRT, %	8.7	6.5	0.57
Postmenopausal, %	76.8	62.9	0.03
Race, %			0.06
White	93.70	91.94	
Black	0.79	1.61	
Hispanic	3.54	3.23	
Asian/Pacific Islander	0.00	3.23	
Other	1.97	0.00	
Operative time, min	145.2	151.9	0.07
Blood loss, mL	48.1	60.4	0.13
Concomitant supracervical hysterectomy, %	74.4	82.3	0.20
Concomitant suburethral sling, %	76.4	79.0	0.66
Concomitant perineorrhaphy, %	18.1	16.1	0.71
PFDI-20	97.7	116.0	0.06
PFIQ-7	58.3	78.1	0.06
Ba, cm	1.0	2.0	0.14
C, cm	-1.0	-1.0	0.97
Genital hiatus, cm, cm	4.0	4.5	0.06
Perineal body, cm	2.4	2.6	0.92
Total vaginal length, cm	9.5	9.5	0.84
Bp, cm	-1.0	-1.0	0.23
Prolapse stage	3.0	3.0	0.29
Clinical cure rate at 12 mo, %	92.4	97.6	0.22

HRT, hormone replacement therapy.

TABLE 3. Subjective and Objective Measures at Baseline and 60 Months or Longer (n = 253)

Variable	Preoperative	≥60 mo	P
PFDI-20	97.71	77.01	<.0001
POPDI-6	39.81	8.41	<.0001
CRADI-8	19.73	40.21	<.0001
UDI-6	37.40	13.69	<.0001
PFIQ-7	58.34	14.02	<.0001
Aa, cm	1.0	-3.0	<.0001
Ba, cm	1.0	-3.0	<.0001
C, cm	-1.0	-8.0	<.0001
Genital hiatus, cm	3.97	3.23	<.0001
Perineal body, cm	2.44	2.78	<.0001
Total vaginal length, cm	9.50	9.35	.0895
Ap, cm	-1.0	-3.0	<.0001
Bp, cm	-1.0	-3.0	<.0001
Prolapse stage	3.0	1.00	<.0001

POPDI-6, pelvic organ distress inventory - 6; CRADI-8, colorectal anal distress inventory - 8; UDI-6, urinary distress inventory - 6.

be true. In fact, the durability of the sacrocolpopexies in this study came at no measured mesh-related costs.

The vast majority of our study patients underwent supracervical hysterectomy, and in every case, the tissue extraction was performed via power morcellation. All of these surgeries were performed before the morcellator controversy. Our group subsequently reported on the rate of occult malignancies (0.5%; ie, 4 of 786 cases) found among all cases of tissue morcellation performed up to the publication of that article.¹⁶ It just so happens that none of the patients in the current sacrocolpopexy study group had occult malignancies.

The strengths of our study include the very large cohort of patients with both subjective and objective follow-up at 5 years or longer, the standardized surgical techniques used, the rigor with which data were collected by nonbiased examiners who were not part of the patients' index surgeries, and our use of validated outcome measures. Nygaard et al⁴ concluded that long-term sacrocolpopexy complication rates and results were disappointing after only getting 28% (90/322) of their original study group back for objective and subjective outcome assessment. We started with roughly the same number of patients as they did, but we achieved 80% (253/316) long-term objective and subjective follow-up. Our composite definition of surgical success was clinically identical to the one used by Nygaard et al.

TABLE 4. Subjective and Objective Measures for the Study Group at 12 Months (or Last Available Measurement) Versus the Last Measures for Those Lost to Follow-up

Variable	Group Lost to Follow-up, n = 63	Group With Postoperative Value ≥ 60 mo, n = 253	P Value (95% CI)
PFDI-20	20.0 (26.2)	20.0 (26.9)	0.99 (-8.0,8.1)
POPDI-6	4.9 (9.1)	5.1 (10.1)	0.87 (-3.2,2.7)
CRADI-8	3.6 (6.8)	6.8 (10.6)	0.01 (-5.5,-0.88)
UDI-6	11.5 (16.3)	8.1 (12.9)	0.15 (-1.3,8.3)
PFIQ-7	5.6 (17.3)	6.8 (22.3)	0.66 (-6.7,4.3)
Aa, cm	-2.5 (-3.0, 0.5)	-3.0 (-3.0, 3.0)	0.41 (-0.3,0.1)
Ba, cm	-2.5 (-3.0, -0.5)	-3.0, (-3.0, 3.0)	0.39 (-0.3,0.1)
C, cm	-8.0 (-10.5, 5.5)	-8.0 (-12.0, -4.0)	0.54 (-0.3,0.5)
Genital hiatus, cm	2.2 (1.1)	2.3 (0.8)	0.47 (-0.4,0.2)
Perineal body, cm	2.6 (0.7)	2.6 (0.7)	0.98 (-0.2,0.2)
Total vaginal length, cm	9.6 (0.9)	9.6 (0.7)	0.55 (-0.3,0.2)
Ap, cm	-2.5 (-3.0, -0.5)	-3.0 (-3.0, 1.0)	0.15 (-0.3,0.0)
Bp, cm	-2.5 (-3.0, -0.5)	-3.0 (-3.0, 1.0)	0.14 (-0.3,0.5)
Prolapse stage	1.0 (0.0, 2.0)	1.0 (0.0, 3.0)	0.6

OPDI - 6, pelvic organ distress inventory - 6; CRADI-8, colorectal anal distress inventory - 8; UDI-6, urinary distress inventory - 6.

The only difference between the 2 definitions was that Nygaard defined POP-Q point C failure as descent beyond the top 1/3 of vaginal length and we defined it as greater than or equal to -5.

Our study weaknesses include the inherent limited generalizability of a single-center study and our lack of a control group. In addition, the age and BMI of our patient population was lower than those reported by other authors.⁴ Although we collected no long-term data for 20% of our potential study group, our comparisons of study participants to nonparticipants suggested minimal selection bias. Our findings are especially important in light of the recent report of much lower surgical success rates among women who underwent vaginal native tissue repairs and were followed with similar outcome measures and for a similar length of time as our group.¹⁵ We believe that women considering surgical correction of POP should be informed of the potential benefits and seemingly limited risks of robotic-assisted laparoscopic sacrocolpopexy as well as the rather disappointing long-term results reported for native tissue POP repair.

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