Porcine Dermis Compared With Polypropylene Mesh for Laparoscopic Sacrocolpopexy

A Randomized Controlled Trial

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OBJECTIVE: To compare the surgical outcomes 12 months after laparoscopic sacrocolpopexy performed with porcine dermis and the current gold standard of polypropylene mesh.

METHODS: Patients scheduled for laparoscopic sacrocolpopexy were eligible for this randomized controlled trial. Both our clinical research nurse and the patients were blinded as to which material was used. Our primary end point was objective anatomic cure defined as no pelvic organ prolapse quantification (POP-Q) points Stage 2 or greater at any postoperative interval. Our sample size calculation called for 57 patients in each group to achieve 90% power to detect a 23% difference in objective anatomic cure at 12 months ($\alpha=0.05$). Our secondary end point was clinical cure. Any patient with a POP-Q point greater than zero, or Point C less than or equal to –5, or any complaints of prolapse symptoms whatsoever on Pelvic Floor Distress Inventory-20 or Pelvic Floor Impact Questionnaire, Short Form 7, or reoperation for prolapse were considered "clinical failures"; the rest were "clinical cures." Statistical comparisons were performed using the χ^2 or independent samples *t* test as appropriate.

RESULTS: As expected, there were no preoperative differences between the porcine (n=57) and mesh (n=58) groups. The 12-month objective anatomic cure rates for the porcine and mesh groups were 80.7% and 86.2%, respectively (*P*=.24), and the "clinical cure" rates for the porcine and mesh groups were 84.2% and 89.7%, respectively (*P*=.96). Pelvic Floor Distress Inventory-20 and Pelvic Floor Impact Questionnaire, Short Form 7 score improvements were significant for both groups with no differences found between groups. There were no major operative complications.

CONCLUSIONS: There were similar outcomes in subjective or objective results 12 months after laparoscopic sacrocolpopexy performed with either porcine dermis or polypropylene mesh.

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LEVEL OF EVIDENCE: I

Pelvic organ prolapse (POP) is a common and debilitating problem the prevalence of which is on the rise.[1] The two main nonsurgical treatment options for POP–pelvic floor muscle strengthening and pessary use–are often either unacceptable to patients or simply unsuccessful, leaving pelvic reconstructive surgery as the only treatment option.[2]

However, once a patient chooses to undergo surgical correction of POP, her decisions have only begun. Some type of "minimally invasive" surgical approach would be the ideal choice for most women, but within the category of "minimally invasive surgery," various tradeoffs must be taken into account. Traditional vaginal operations that rely solely on a patient's own connective tissue, while minimally invasive, have been associated with higher failure rates

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than operations that incorporate polypropylene mesh.[3] However, the use of synthetic grafts (especially transvaginal mesh) adds unique complication risks.[4,5]

One tried-and-true POP repair option–sacrocolpopexy–involves suspension of the vagina to the anterior longitudinal ligament near the sacral promontory through a Y-shaped synthetic or biologic graft material. This de facto "gold standard" operation was first described as an open abdominal procedure but is increasingly performed laparoscopically (either with or without robotic assistance). Cure rates associated with the sacrocolpopexy are quite high, but even this widely touted operation can result in synthetic mesh-related complications such as graft erosion, extrusion, or pain.[6] Some surgeons have used nonpermanent biologic grafts (such as cadaveric fascia lata and small intestine submucosa) in an effort to reduce the risk of these graft-related complications. However, this potential benefit has come at the price of higher anatomic failure rates as compared with synthetic mesh.[2]

Other biologic graft materials are chemically crosslinked in hopes of making them behave more like permanent materials. One such product, crosslinked acellular porcine dermis (Pelvicol), is functionally nonporous and is therefore fully encapsulated during the healing process.[7] Perhaps as a result of this encapsulation, it performed poorly when used for abdominal sacrocolpopexy.[8] Other studies demonstrated surgical success rates between 81% and 87% at follow-up intervals lasting 2–5 years when Pelvicol was used to augment vaginal prolapse repairs.[9,10] More recently, a meshed version of that same material (PelviSoft acellular collagen matrix) was characterized by a much more favorable host response, a combination of tissue in-growth and encapsulation.[11] When designing this study, we hypothesized that this more favorable host response could potentially result in better sacrocolpopexy outcomes than those reported with nonmeshed Pelvicol.[8]

Nevertheless, type 1 polypropylene mesh[12] is so widely accepted as the material of choice for sacrocolpopexy that any new graft materials should be compared with it before widespread adoption.

With that in mind, our study objective was to compare the objective and subjective surgical outcomes 12 months after laparoscopic sacrocolpopexy performed with porcine dermis (PelviSoft) or type 1 polypropylene mesh.

MATERIALS AND METHODS

The Atlantic Health System institutional review board approved this study (study number R05-11-004), which was a double-blind, randomized controlled trial that compared an organic graft with a synthetic graft for laparoscopic sacrocolpopexy. The trial details were posted on the web site www.clinicaltrials.gov (identifier number NCT00564083).

All women scheduled to undergo laparoscopic sacrocolpopexy for the treatment of Stage II or greater apical POP at our institution between 2006 and 2008 were eligible. Exclusion criteria included pregnancy or desire for future pregnancy, prior sacrocolpopexy, and any prior POP repair that incorporated synthetic mesh. All eligible patients first went through our usual informed consent process followed by a separate, study-specific informed consent process conducted by our clinical research nurse. Patients agreed to both the randomization process and to being blinded to their group assignment throughout the 12-month study period. All participants were told that the porcine material could prove to be inferior and that its potential benefits were theoretical. In an effort to prove that we did not demonstrate selection bias when determining our study group, we compared the demographics of our study participants with those who were eligible but declined. During the study period, we used the polypropylene mesh as our "default" material, meaning that only study participants had the possibility of undergoing a sacrocolpopexy using the porcine material.

Randomization was carried out using a computerized blocked sequence generation using blocks of six. Our statistician (J.L.P.) created sequentially numbered opaque sealed envelopes to conceal the group assignments until the immediate preoperative time period, and she controlled the master list throughout the study period. To avoid the possibility of patient steering, only the statistician knew the block size used for the randomization scheme. Immediately before each operation, the attending surgeon opened the patient's envelope to determine which graft material to use. For each patient, only the surgical team was aware of the particular graft material used. The type of graft material used for each case was only recorded in the dictated operative note, and these notes were kept from the clinical research nurse.

Regardless of graft material type, the operations were carried out using one standardized surgical technique. At the outset of the study, we had been exclusively performing traditional "straight stick" laparoscopic sacrocolpopexies and were well through our learning curve for that operation. Then approximately 6 months into this study period, we began using robotic assistance to perform the same laparoscopic techniques we had been using all along.

Therefore, the only true robotic learning curve that happened during the study period had to do with the technical aspects of using the robotic equipment.

A detailed description of the standardized surgical technique we used has been previously published.[13] The polypropylene mesh we used started as an 8×15-cm sheet (Pelvitex), and the crosslinked porcine dermis graft started as an 8×12-cm sheet (PelviSoft acellular collagen matrix). We prepared the polypropylene and porcine grafts identically, sewing them into a Y shape before insertion into the peritoneal cavity. Each Y graft of either type was customized to the size of that patient's specific anterior and posterior defect. The posterior arms of the Y grafts were generally 8–10 cm in length, so that they could reach to the perineum (or at least to within 1 cm from it). The anterior arms were between 4 and 7 cm in length so that they could reach to the area of the vaginal wall just proximal to the trigone.

For patients with a uterus, supracervical hysterectomies were performed as the first surgical step. In these cases, uterine morcellation was performed as the last laparoscopic step. We fastened the posterior portion of each graft in place first using anywhere from six to 10 interrupted polytetrafluoroethylene sutures. We then fastened the grafts to the anterior vaginal wall using between six and 10 polytetrafluoroethylene sutures. The appropriate graft tensioning was determined by palpation of the vagina after completion of graft fixation to the vagina. The proximal aspect of the Y graft was sutured to the anterior longitudinal ligament of the sacrum at the level of the promontory or just below that level. Two zero-gauge permanent sutures were used at the sacral level. The grafts were then retroperitonealized using a running suture of delayed absorbable zero gauge suture. All concomitant continence surgeries were retropubic midurethral tension-free slings. The only other concomitant surgeries performed were perineorrhaphies at the discretion of the attending surgeon.

All preoperative and 1-year postoperative outcome measures were collected by a single, blinded urogynecology clinical research nurse. We chose our 1-year study period based on evidence that almost all prolapse recurrence after a sacrocolpopexy happens within that timeframe.[14,15] The specific outcome measures collected included relevant demographic and perioperative data; pelvic organ prolapse quantification (POP-Q) measurements[16]; the Pelvic Floor Distress Inventory, Short Form 20 and the Pelvic Floor Impact Questionnaire, Short Form 7[17]; a validated prolapse-specific surgical satisfaction questionnaire[18]; a prolapse-specific sexual function questionnaire[19]; and a visual faces pain scale regarding pelvic and low-back pain.[20]

Our primary outcome was "objective anatomic cure" based on all postoperative POP-Q measurements falling within stage O or I.[21] Because that definition potentially allowed for significant apical descent (even for those deemed "cured"), we added a component, namely that POP-Q point C had to be −5 or less.

Based on findings of Swift et al,[22] we added a second definition of surgical cure. These authors found that patients rarely experienced prolapse symptoms until the leading edge of their defect bulged beyond the opening of the vagina. Barber et al[23] reported similar findings and recommended using definitions of surgical success that take both objective and subjective measures into account. We therefore defined "clinical cure" by considering POP-Q measures and subjective findings simultaneously.

To meet our definition of "clinical cure" at 1 year, all of the following were required: 1) POP-Q point C −5 or less; 2) no POP-Q point could be greater than 0; 3) no prolapse symptoms could be reported on the Pelvic Floor Distress Inventory-20 or Pelvic Floor Impact Questionnaire, Short Form 7; 4) The surgical satisfaction questionnaire answer had to be "satisfied" or "very satisfied"; and 5) no reoperation for POP could have taken place. Unless all five criteria were met, the patient was placed into the "clinical failure" category; the rest were "clinical cures." We set up this alternative definition of surgical cure before our statistical analysis, and we decided to report it alongside the "objective anatomic cure."

Our main secondary end points included the total scores and subscales of the Pelvic Floor Distress Inventory-20, Pelvic Floor Impact Questionnaire, Short Form 7. We also collected preoperative and postoperative Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire-12 scores; and Sandvik Index[24] scores for urinary incontinence.

Using the Sandvik Index, we performed an analysis similar to the one reported in the colpopexy and urinary reduction efforts (CARE) trial.[25] Based on the CARE trial findings, we offered slings to patients without clinical or urodynamic stress incontinence and compared the postoperative Sandvik Index scores within this subgroup for those who did and did not opt for sling placement. We also used the Sandvik Index to define all patients as either "clinically dry" or not at 12 months. Our definition of "clinically dry" was a Sandvik Index score of 3 or less along with no use of absorbent pads as previously reported.[26]

Because our study included both traditional straight stick and robotic-assisted laparoscopic sacrocolpopexies, we looked for clinically important differences between these approaches with respect to relevant perioperative and postoperative variables. For the purposes of this study–to facilitate comparisons between the two laparoscopic approaches–we defined "operative time" as the interval from initial incision to the moment all of the trocars were removed (which of course included any robot-specific activities such as docking as well as uterine morcellation when applicable). We excluded the time for sling placement or perineorrhaphy performance from the "operative time" definition, because those parts of the cases often happened simultaneous to uterine morcellation or trocar site closure. We further compared cases involving supracervical hysterectomy with post-hysterectomy cases in terms of operative time, blood loss, and adverse events.

We tracked the following surgical complications and adverse events: mesh or graft exposure or erosion, need for sling revision; de novo dyspareunia, surgical site infection, reoperation for prolapse, readmission to the hospital for anything related to the index surgery, blood transfusion, conversion to laparotomy or vaginal route, and ileus.

Our sample size was determined using data from our previously published randomized controlled trial comparing polypropylene mesh and cadaveric fascia lata for open sacrocolpopexies.[27] In that study, we found cure rates of 91% and 68% among the mesh and fascia lata groups, respectively. We therefore powered the current study to have a 90% chance of detecting that same 23% difference with an α of 0.05. To achieve this power, we needed 57 patients per group. We estimated a loss-to-follow-up rate of 5%, so we planned to recruit 120 patients.

Statistical analysis was performed using standard statistical software (SAS 9.1). Preoperative and postoperative POP-Q points and questionnaire values were compared using paired *t* tests. Comparisons between categorical variables were performed using χ^2 and, for nonparametric continuous and ordinal values, the Mann-Whitney *U* test. Univariable analyses were performed for the variables, all thought to be predictive of surgical success or failure. These possible covariates were screened by using a *P* value of .25, such that any predictors reaching that threshold be admitted into a multivariable analysis.

RESULTS

Between 2006 and 2008, 184 patients were eligible and 120 enrolled. A total of 115 patients (57 in the porcine dermis group and 58 in the synthetic mesh group) completed the full 12 months of follow-up visits. One patient in the porcine group could not tolerate a pneumoperitoneum and was therefore converted to a vaginal approach (and removed from the study). Figure 1 depicts a flow diagram of the enrollment and study period. There were no demographic differences between the study participants and those who declined (Table 1). Preoperative demographic characteristics of the study group are in Table 2. Figure 1 depicts a flow diagram of the enrollment and study period. Table 3 includes all information about our primary results. The cure rates between groups were not significantly different. The "objective anatomic cure" rates for the porcine and synthetic mesh groups were 80.7% and 86.2%, respectively (P=.24). Using our "clinical cure" definition, the cure rates for the porcine and synthetic mesh groups were 84.2% and 89.7%, respectively (P=.96). We found no differences between groups for any individual POP-Q points. Figures 2, 3, and 4 illustrate the similarities of the mean values over time between groups for POP-Q points Ba, C, and Bp. In univariable analyses, no variables met the threshold of P<.25, so no multivariable analysis was required.

There were no apical (ie, point C) failures in either group. All failures were either cystoceles or rectoceles that occurred distal to the edges of the graft material. In the porcine group, there was a total of seven cystoceles and two rectoceles beyond the introitus. In the synthetic mesh group, there was

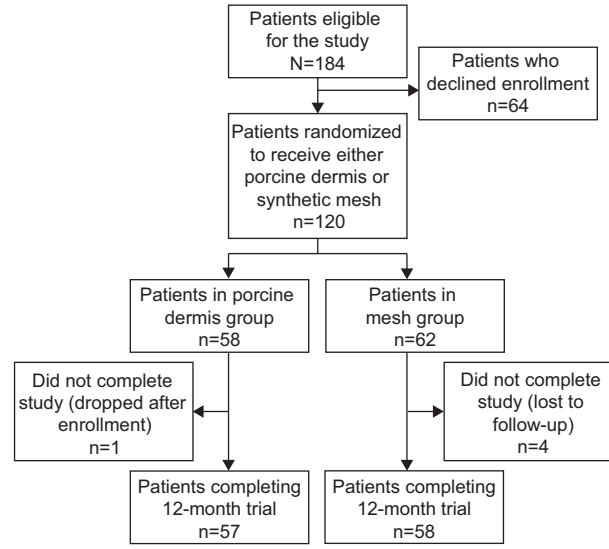

Fig. 1. Enrollment and follow-up of our study population.
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Table 1. Demographic Characteristics of the Total Study Group and Those Patients Who Declined Enrollment During the Study Period

	Eligible Patients Who Declined Enrollment (n=64)	Total No. of Study Patients (N=119)	*P*
Age (y)	54.4±10.2	56.9±8.4	.10
Body mass index (kg/m^2)	25.6±3.8	25.2±3.3	.51
Smoking (% smokers)	6.2 (4/64)	5.9 (7/119)	.92
Race (% white)	89 (57/64)	93.3 (111/119)	.32
Preoperative Aa (cm)	0.5±1.8	1.0±1.7	.12
Preoperative Ba (cm)	1.6±2.2	2.0±2.2	.29
Preoperative Ap (cm)	−0.7±1.4	−0.8+1.3	.83
Preoperative Bp (cm)	−0.2±2.2	−0.5±2.1	.38
Preoperative C (cm)	0.0±3.5	−1.0±3.6	.07
Preoperative total vaginal length (cm)	9.2±1.1	9.2±0.9	.99
Preoperative prolapse stage	2.7±0.6	2.6±0.6	.52
Preoperative Pelvic Floor Distress Inventory-20 (short form)[15] total score	NA	113.6±55.5	NA
Preoperative Pelvic Floor Impact Questionnaire (short form)[15] total score	NA	72.6±61.9	NA
Vaginal parity	2.4±1.0	2.5±1.3	.74
Prior prolapse surgery	31.2 (20/64)	24.4 (29/119)	.33
Patients postmenopausal	71.9 (46/64)	80.7 (96/119)	.17
Patients on systemic hormone therapy	9.4 (6/64)	14.3 (17/119)	.34

Aa and Ba, 2 points along the anterior vaginal wall; Ap and Bp, 2 points along the posterior vaginal wall; C, the vaginal cuff; NA, not applicable.
Data are mean ± standard deviation or % (n/N) unless otherwise specified.

Table 2. Preoperative Demographic Information for the Porcine Dermis and Polypropylene Mesh Groups

	Porcine Dermis (n=57)	Polypropylene Mesh (n=62)	*P*
Age (y)	57.7±8.3	56.2±8.5	.32
Body mass index (kg/m^2)	24.8±3.0	25.6±3.6	.21
Smoking (% smokers)	7.0 (4/57)	4.8 (3/62)	.61
Race (% white)	95 (54/57)	92 (57/62)	.54
Vaginal parity	2.6±1.1	2.4±1.4	.49
Incontinence severity index	3.3±3.8	3.3±3.2	.95
Preoperative Aa (cm)	1.2±1.5	0.7±1.8	.08
Preoperative Ba (cm)	2.1±2.3	1.8±2.2	.55
Preoperative C (cm)	−1.2±3.9	−0.8±3.4	.50
Preoperative genital hiatus (cm)	3.8±1.4	3.9±1.5	.69
Preoperative perineal body (cm)	2.4±0.7	2.5±0.7	.32
Preoperative total vaginal length (cm)	9.3±1.0	9.1±0.8	.19
Preoperative Ap (cm)	−0.7±1.3	−0.8±1.3	.92
Preoperative Bp (cm)	−0.6±1.9	−0.3±2.2	.45
Preoperative prolapse stage	2.7±0.6	2.6±0.6	.34
Pelvic Floor Distress Inventory-20 (short form)[15] total score	113.4±64.5	113.8±46.3	.96
Pelvic Floor Impact Questionnaire (short form)[15] total score	72.2±65.4	72.9±59.0	.96
Prior continence surgery	10.5 (6/57)	8.1 (5/62)	.64
Prior prolapse surgery	21.0 (12/57)	27.4 (17/62)	.45
Patients postmenopausal	82.5 (47/57)	79.0 (49/62)	.64
Patients on systemic hormone therapy	17.5 (10/57)	11.3 (7/62)	.33
Patients with prior hysterectomy	28.1 (16/57)	24.2 (15/62)	.63

Aa and Ba, 2 points along the anterior vaginal wall; C, the vaginal cuff; Ap and Bp, 2 points along the posterior vaginal wall.
Data are mean ± standard deviation or % (n/N) unless otherwise specified.

Table 3. Cure Rates, Subjective Improvement, and Improvement in Sexual Function 12 Months After Laparoscopic Sacrocolpopexy

	Total No. of Study Patients (N=115)	Porcine (n=57)	Mesh (n=58)	*P*
Objective cure*	83.5 (96/115)	80.7 (46/57)	86.2 (50/58)	.24
Clinical cure†	87.0 (100/115)	84.2 (48/57)	89.7 (52/58)	.96
Pelvic Floor Disorders Inventory-20[15] improvement	69.1 (84.3±53.8)	60.6 (81.1±63.4)	77.3 (87.4±42.9)	.54
Pelvic Floor Impact Questionnaire-7[15] improvement	80.0 (59.6±61.4)	74.6 (56.1±60.2)	84.8 (63.0±62.9)	.55
Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire-12 improvement	15.1 (4.21±5.7)	12.5 (3.3±5.8)	17.3 (4.9±5.5)	.18

Data are % (n/N) or mean ± standard deviation unless otherwise specified.
* Defined as pelvic organ prolapse quantification (POP-Q) Stage 0 or 1 and POP-Q point C −5 or less.
† Defined as no POP-Q point greater than 0; POP-Q point C −5 or less, and no pelvic organ prolapse symptoms on Pelvic Floor Distress Inventory-20 (short form).[15]

a total of three cystoceles and three rectoceles beyond the introitus.

We found no differences between the porcine and synthetic mesh groups for any of our secondary outcome measures. When comparing preoperative with 12-month postoperative scores, Pelvic Floor Distress Inventory-20, Pelvic Floor Impact Questionnaire, Short Form 7, and Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire-12 values improved for all patients, and there were no differences between the porcine and synthetic mesh groups with respect to any of these scores. The percentage improvements seen in these scores are also in Table 3.

Overall, 59% of the patients (70 of 119) underwent suburethral sling placement at the time of sacrocolpopexy. Of these, 91.4% were "clinically dry" at 12 months compared with a 77.6% "clinically dry" rate for those who did not get a sling (*P*=.03). As for the repeat CARE trial analysis, there were 23 patients who reported no preoperative stress incontinence and also had negative urodynamic findings for stress incontinence, and all of them were offered concomitant suburethral sling placement. Of these, 16 opted for sling placement. The mean Sandvik Index scores were 10.2±13.2 and 16±13.2 and for the 16 sling and seven no-sling groups, respectively (*P*=.04) indicating more urinary incontinence among the no-sling group.

Very few adverse events occurred, making statistical analysis of adverse events between groups impossible. Four patients who had declined concomitant suburethral sling placement opted to have one placed after developing postoperative stress incontinence. Only one patient in the porcine dermis group and none in the polypropylene group experienced mesh exposure. One patient (in the porcine group) required a single steroid injection at the vaginal apex

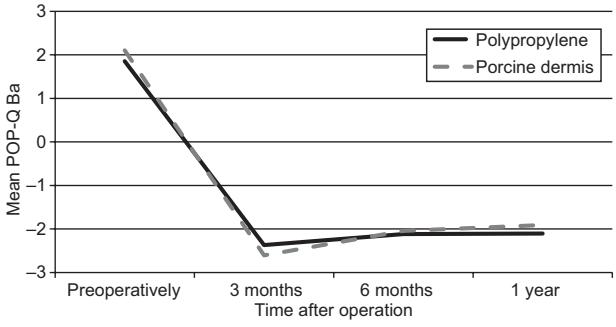

Fig. 2. Mean pelvic organ prolapse quantification (POP-Q) point Ba graphed over 1 postoperative year for the mesh group (*solid line*) and the porcine dermis group (*dashed line*).

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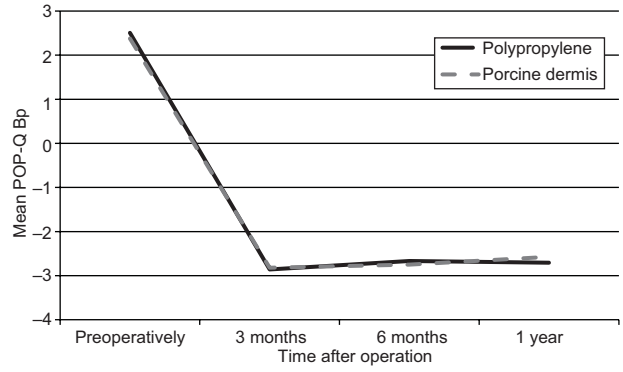

Fig. 3. Mean pelvic organ prolapse quantification (POP-Q) point Bp graphed over 1 postoperative year for the mesh group (*solid line*) and the porcine dermis group (*dashed line*).

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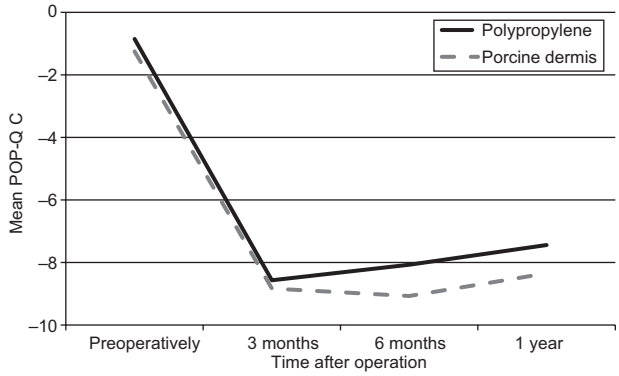

Fig. 4. Mean pelvic organ prolapse quantification (POP-Q) point C graphed over 1 postoperative year for the mesh group (*solid line*) and the porcine dermis group (*dashed line*).

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as a treatment for dyspareunia. Only five patients (5.2%) reported de novo dyspareunia, two in the porcine group and three in the synthetic mesh group (P=.49). We compared rates of de novo dyspareunia among patients who received perineorrhaphy (n=26) with those who did not (n=93). The de novo dyspareunia rates for the perineorrhaphy and no-perineorrhaphy groups were 13.3% and 2.3%, respectively (P=.19). There were no readmissions, postoperative ileus, febrile morbidity, bladder injuries, bowel injuries, blood transfusions, or conversions to laparotomy in either group, and all patients in both groups were discharged on postoperative day 1. There were no differences between groups with respect to concomitant perineorrhaphies performed or suburethral slings placed.

Of the 119 study surgeries, 95 were robotic-assisted and 24 were done using the traditional straight stick laparoscopic approach. The choice between these two approaches was at the discretion of the attending surgeon. These straight stick cases represented 14% of the porcine group and 26% of the mesh group (P=.11). We found no clinically important differences between these two laparoscopic approaches. The mean operative times for robotic-assisted cases and straight stick cases were 183.4 minutes and 190.6 minutes, respectively (P=.53). Despite including the extra steps of supracervical hysterectomy and uterine morcellation, the mean operative time for patients with and without a uterus present was clinically similar but statistically different. The mean operative times (in minutes) for patients with and without a uterus was 189 and 180 (P=.03). The mean blood loss values for the robotic-assisted and straight stick cases were 56±40 mL and 89±83 mL, respectively (P=.07).

DISCUSSION

The ongoing controversy regarding the use of synthetic mesh for repair of POP has prompted many surgeons to look for an acceptable biologic graft material that can be used for any surgical approach (ie, vaginal, abdominal or laparoscopic). Any such material should be compared with the gold standard (type 1 polypropylene mesh) through randomized trials. Having done just that, we could not find any differences in subjective or objective results 12 months after laparoscopic sacrocolpopexy performed with either crosslinked porcine dermis or polypropylene mesh. Our surgical cure rates (regardless of the definition used) did not differ between groups. The 12-month scores for the surgical satisfaction questionnaire seemed to validate our "clinical cure" definition, because each of the patients we deemed "clinical cures" or "clinical failures" reported satisfaction or dissatisfaction, respectively.

The strengths of our study included the double-blind, randomized design; the use of subjective as well as objective outcome measures; the use of surgical satisfaction scores; our very small rate of attrition; and our use of a standardized surgical technique.

Our study had some obvious weaknesses as well. Some may consider our sample size relatively small, but we did achieve 90% power to detect the same difference we previously reported between biologic and synthetic grafts for sacrocolpopexy. Our 12-month follow-up interval was a limitation. Although a longer follow-up period would have provided more meaningful results, the tradeoff would have undoubtedly involved greater attrition rates. Furthermore, the vast majority of POP surgical failures happen within the 12-month postoperative window.[14,15] One could also argue that our study population was not surgically homogenous, because we used both robotic assistance and straight stick techniques, yet we found no clinical differences between these two surgical approaches. One could also argue that our results are not externally valid (ie, generalizable), but such a criticism can almost always be made for a surgical trial. The only way we could have guarded against such criticism would have been to include more study centers, but doing so would have undoubtedly diminished our ability to standardize our surgical techniques. Therefore, our results should only be applied to the specific surgical techniques we used for these patients. Our two study materials could, in fact, perform differently when used other ways.

In light of our previous study comparing fascia lata with mesh, our results are especially important,

because some authors have been citing those results to make a case for the inferiority of biologic grafts as a whole. Now, however, it seems more appropriate to make judgments about biologic grafts on a case-by-case basis.

So why did this particular biologic mesh seem to work better than cadaveric fascia lata? Perhaps the chemical crosslinking played a role. Fenestrated acellular crosslinked porcine dermis has been previously shown to undergo both tissue in-growth and encapsulation during the healing process after reconstructive pelvic surgery.[11] Perhaps these characteristics are beneficial when compared with the process of "tissue remodeling" that seems to characterize other noncrosslinked biologic graft materials. Other unmeasured factors may have also played a role, but regardless of the reason, we found no differences between crosslinked fenestrated acellular porcine dermis and type 1 polypropylene mesh for the laparoscopic (and robotic-assisted) sacrocolpopexy. We intend to follow these patients to determine whether these results will be sustained over a longer term.

Based on our study results, our group continues to use PelviSoft for robotic-assisted sacrocolpopexies in selected cases. For example, when we perform a concomitant total (rather than supracervical) hysterectomy, we will often use the porcine material in hopes of mitigating the risk of mesh exposure. Also, this porcine dermis is a good alternative graft material for patients undergoing sacrocolpopexy who simply do not want to receive synthetic mesh. However, our group still uses synthetic mesh as our default graft material, mainly because it is less expensive than porcine dermis.

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