A Randomized Controlled Trial Comparing Fascia Lata and Synthetic Mesh for Sacral Colpopexy

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Objective: To compare the objective anatomic outcomes after sacral colpopexy performed with cadaveric fascia lata and polypropylene mesh.

Methods: Patients undergoing a sacral colpopexy were randomized to receive either fascia lata or polypropylene mesh in a double-blinded fashion. Data were collected at 6 weeks, 3 months, 6 months, and 1 year postoperatively. The main outcome measures were pelvic organ prolapse quantification (POP-Q) system stage and individual POP-Q points over time. Objective anatomic failure was defined as POP-Q stage 2 or more at any point during the follow-up period. Proportions of patients with objective anatomic failure at 1 year in each group were compared using the χ^2 test. Mean POP-Q points and stage at 1 year were compared by using the independent samples *t* test.

Results: One hundred patients were randomized to receive either fascia (n = 46) or mesh (n = 54). Of the 89 patients returning for 1-year follow-up, 91% (41/45) of the mesh group and 68% (30/44) of the fascia group were classified as objectively cured (P = .007). We found significant differences between the mesh and fascia groups with respect to the 1-year postoperative comparisons of points Aa, C, and POP-Q stage. There were no differences between the 2 groups with respect to points TVL (total vaginal length), GH (genital hiatus), PB (perineal body), Ap or Bp (2 points along the posterior vaginal wall).

Conclusions: Polypropylene mesh was superior to fascia lata in terms of POP-Q points, POP-Q stage, and objective anatomic failure rates.

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Level of Evidence: I

Pelvic organ prolapse is a common medical condition, the prevalence of which increases with advancing age.[1] In this country, at least 200,000 operations for the correction of prolapse are performed each year,[2] and as the proportion of elderly women in the United States rises, the demand for surgery to correct prolapse will increase dramatically.[3] Although no specific operation for the correction of pelvic organ prolapse can truly be considered the "gold standard," abdominal sacral colpopexy was recently dubbed the "main abdominal approach" for prolapse surgery by 1 group of experts.[4] This distinction seems appropriate, given that reported prolapse cure rates among sacral colpopexy studies with more than 200 patients range from 85% to 100%.[5–7]

There is no consensus among experts as to the best graft material for this operation. Characteristics of an ideal graft material would include consistent durability and quality, reasonable cost, resistance to host absorption, minimal risk of erosion or infection, and restoration of normal functional anatomy. Although no such "perfect" material exists, the majority of sacral colpopexies reported in the literature have been performed with synthetic meshes.[4] Two of the most common adverse events related to synthetic mesh used for sacral colpopexy are mesh erosion (0.5–5.0%) and dyspareunia (14%).[4,8] In an effort to minimize the incidence of these and other complica-

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tions, many surgeons have chosen to use biologic graft materials such as cadaveric fascia lata. However, some retrospective reports have suggested that colpopexies performed with fascia lata have unacceptably high failure rates.[9–11]

In the absence of level-1 evidence, surgeons have been forced to choose among the wide variety of synthetic and biologic materials primarily by considering the theoretical advantages and disadvantages each. With this in mind, our objective was to compare the objective anatomic failure rates after sacral colpopexy performed with 2 of the most commonly used graft materials: solvent-dehydrated cadaveric fascia lata and polypropylene mesh.

MATERIALS AND METHODS

The University of Louisville Human Studies Committee approved this study, which was a double-blinded, randomized, controlled trial comparing polypropylene mesh and cadaveric fascia lata for sacral colpopexy. Eligible patients included women with posthysterectomy vaginal vault prolapse scheduled for sacral colpopexy through the Division of Urogynecology and Reconstructive Pelvic Surgery at the University of Louisville Health Sciences Center. All patients went through a routine informed consent process, during which surgical and nonsurgical options were discussed. After selecting sacral colpopexy as the treatment for pelvic organ prolapse, each patient went through a separate informed consent process for the study itself.

For those patients agreeing to participate, a computerized blocked randomization scheme (using blocks of 8) was constructed to determine the type of material that would be used for the sacral colpopexy. The master list for the randomization scheme generated was held by the statistician. The researchers received only a stack of 104 opaque, numbered, sealed envelopes, each containing the assignment for the subject number on the outside of the envelope. To avoid the possibility of patient steering, the researchers were unaware of the block size. Each patient's envelope was opened immediately before her surgery.

Throughout the 1-year study period, only a given patient's surgical team was aware of her group assignment, and all preoperative and postoperative outcome measures were obtained by a single blinded examiner (L.B.). Patients were told which material they had received only after they had completed the 1-year follow-up period.

We used the following procedures to maintain the double-blinding within the study: The actual material used for a given colpopexy appeared in only 2 places: the dictated operative note and the master list of the randomization scheme. All patients were made aware of the importance of their not knowing which material had been used for their surgery. The certified clinical research nurse (L.B.) who collected all of the data throughout the study period did not have access to the dictated operative notes or the master list of the randomization scheme. During each surgery, members of the surgical team were reminded not to reveal the nature of the material used to the patient.

The primary outcome measure of interest was the percentage of anatomic outcome failures for our 2 groups as defined by Weber et al,[12] using the ordinal staging of the pelvic organ prolapse quantification (POP-Q) system[13] for assessment.

In the following manner, our certified clinical research nurse (L.B.) was trained to perform POP-Q point measurements. First, the clinical research nurse reviewed the video entitled "Pelvic Organ Prolapse Quantification Examination," developed by Dr. Richard Bump and available for purchase from the American Urogynecologic Society on their Web site (http://www.augs.org). Second, during the preoperative period the clinical research nurse observed several POP-Q examinations by each of the investigators of females with pelvic organ prolapse. Finally, she performed several POP-Q examinations of females with pelvic organ prolapse during the preoperative period while being observed by each of the investigators.

For the study itself, the clinical research nurse performed POP-Q measurements preoperatively at enrollment, and postoperatively at the 6-week, 3-month, 6-month, and 12-month points. She also collected preoperative POP-Q values for the group of patients who were offered enrollment in the study but chose not to participate.

Secondary endpoints (collected at baseline and at the above-mentioned intervals throughout the postoperative period) included the following validated assessment tools: a prolapse symptom inventory and quality of life scale (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 organ prolapse [abstract]. J Urol 2000;163:76); a pelvic organ prolapse/urinary incontinence sexual questionnaire[14]; a urinary incontinence severity index[15]; a visual faces pain scale[16]; a constipation severity score; and a defecation diary.[17]

Preoperative information (collected for the study group as well as all other eligible patients) included age, body mass index, gravity, parity, menopausal status, hormone replacement status, any prior prolapse or continence surgery, and diabetic status.

Intraoperative information collected for all eligible patients included estimated blood loss, need for intraoperative blood transfusion, duration of surgery,

and concomitant prolapse or continence operations performed along with the sacral colpopexy. The study coordinator also collected information regarding the immediate postoperative course and adverse events throughout the first postoperative year for all study patients (but not those who declined enrollment).

We used polypropylene mesh as the "default" material during the study period. In other words, only those women participating in the study had a chance of receiving a colpopexy performed with fascia lata. Any woman who underwent a sacral colpopexy outside of the study received polypropylene mesh.

All patients underwent a comprehensive urogynecologic assessment, including detailed history/physical examination and multichannel urodynamic studies with support of the vaginal vault. Based on the urodynamic studies, each surgeon decided preoperatively whether to perform concomitant continence surgery on a case-by-case basis.

All surgeries followed the same general principals outlined below. With the patients in Allen universal stirrups (Allen Medical Systems, Bedford Heights, OH), the prolapsed vaginal wall was replaced with a Lucite vaginal dilator (Progressive Medical Instruments, Louisville, KY). A self-retaining retractor was used to hold the intestines in the upper abdomen and retract the sigmoid colon to the left pelvic sidewall. After the peritoneum overlying the sacral promontory was incised, careful sharp and blunt dissection was used to expose the anterior longitudinal ligament of the sacrum at the S1 to S2 level. Two to three polytetrafluoroethylene sutures (Gore-Tex CV-2, W. L. Gore & Associates, Flagstaff, AZ) were placed through this ligament. Next the peritoneal incision was extended down the right paracolic gutter to the level of the vaginal cuff. The vesico-vaginal and recto-vaginal spaces were then developed sharply and bluntly, such that the entire area of poorly supported vagina (on both the anterior and posterior sides) was exposed. Two separate pieces of surgical graft material were used for each colpopexy. Those randomized to the "mesh" group received polypropylene (Trelex; Boston Scientific, Boston, MA), and those randomized to the "fascia" group received solvent dehydrated cadaveric fascia lata (Tutoplast processed Suspend fascia lata; Mentor Corporation, Santa Barbara, CA). Three to five rows of Gore-Tex sutures (3 sutures per row) were used to fasten one piece of graft material to the anterior vaginal wall. A separate piece of graft material was then attached to the posterior vaginal wall with 3–6 rows of Gore-Tex sutures (2 sutures per row), usually extending down one half to two thirds of the vaginal length. The 2 pieces of material were then fastened together with permanent sutures to form a Y-shape. The proximal end of this Y-shaped graft was then attached to the previously placed presacral Gore-Tex sutures. The graft material was then completely covered with peritoneum. No separate culdoplasty procedures (such as a Halban or Moschowitz) were performed.

Concomitant prolapse and/or continence surgeries were then completed according to the judgment of the attending physician. These concomitant operations included tension-free vaginal tape procedures (for patients diagnosed with stress incontinence on preoperative urodynamic studies), paravaginal repairs (based on the attending surgeons' intraoperative judgment), and posterior repairs (again, based on the attending surgeons' intraoperative judgment). Cystoscopy was performed at the end of each surgery to ensure that the lower urinary tract was free from damage. We asked all patients to comply with our standard postoperative restrictions for 3 months after surgery. These restrictions included lifting no more than 8 pounds, refraining from sexual intercourse, refraining from all exercise other than walking, and refraining from excessive straining with bowel movements. All patients were asked to use a stool softener for 3 months after surgery.

Before the start of the study, we decided that a 30% difference in POP-Q values between the 2 groups over the course of 1 postoperative year would be clinically important. We used data from a pilot study of 20 patients who underwent sacral colpopexy with biologic material to estimate standard deviations and correlations for power and sample size calculations. We hypothesized for sample size determination purposes that 1 group would remain unchanged while the other increased 30%. By using the general linear models theory of repeated measures, this was shown to be equivalent to estimating the sample size for a 1-group t test comparing the mean equal to zero with the true mean equal to 0.522 and variance equal to 0.2348. This calculation resulted in an initial sample size estimate of 20 per group for 90% power. After some sensitivity analysis to account for possibly increased variance and using the interim analysis sample size software (Lan-DeMets 2.1; Lan-DeMets, Madison, WI) to adjust the sample size and analysis method for one interim look, we increased the sample size to 30 per group to achieve a 90% power for detecting that difference with an α value of 0.05 (a 2-sided test), using the repeated measures analysis of variance test to detect a linear difference in mean POP-Q point values over 1 year. The interim look at the data was scheduled to be performed when half of the study group had completed their 1-year follow-up period. Finally, to allow for possible loss to follow-up, 50 patients per group were recruited. The planned interim analysis was never performed because the

duration of the recruitment period was shorter than expected. By the time that 50% of the group had completed their 1-year follow-up, the entire sample size of 100 had been accrued. Therefore, we decided to forgo the interim analysis because that would have complicated the data analysis without the possibility of shortening patient recruitment.

Detailed histograms were created to assess the normality of the data. Because this initial analysis revealed that the data were not Gaussian in distribution, we were not able to use the repeated measures analysis of variance test as planned. A gamma distribution[18] better described most of the POP-Q points after surgery, which led us to use the generalized estimating equation methodology[19] to compare these measurements over time. The advantage of using the generalized estimating equation and mixed model methodology to answer the repeated measures questions of differences over time was that it automatically included data until the subject was lost to follow-up. That is, these statistical methods made optimal use of even partial data. The Poisson distribution best described POP-Q stage for the generalized estimating equation. The sample size of 100 was adequate for score tests in the generalized estimating equation, which allows use of incomplete data in a longitudinal study. That is why the final sample size for generalized estimating equation was 100. Likewise, a mixed models analysis of variance was used for the POP-Q measurement point C.

Based on the recommendations of Weber et al,[12] objective anatomic failure was defined as a POP-Q stage of 2 or greater found at any postoperative interval. In other words, if any POP-Q point along the apex, anterior, or posterior vaginal wall measured –1 or more, that patient was classified as an objective anatomic "failure." The 2 groups' objective anatomic failure rates at 1 year were compared using the χ^2 test.

Demographic variables and preoperative POP-Q scores were compared between the "fascia" and "mesh" groups by using the Mann-Whitney *U* nonparametric test for continuous and ordinal variables and the χ^2 test for categorical variables. The POP-Q points at 1 year were compared by using the Mann-Whitney *U* test.

Univariate analyses were performed on variables thought to be potential predictors of objective anatomic failure, namely, surgical material, age, body mass index (BMI), previous prolapse or continence surgery, and whether a paravaginal repair was performed along with the colpopexy. These possible covariates were screened by using $P = .25$. If a covariate did not have $P \leq .25$, it was not admitted into the list of possible predictor candidates. Our smallest *P* value was .22, and, because our study was randomized and we did have statistical significance, we did not proceed with multivariate analyses for any of these covariates.

RESULTS

Between July 2001 and June 2003, 100 patients were enrolled in the study. During that same time interval, 101 patients undergoing sacral colpopexy through our practice were offered enrollment but refused to participate in the study. Although the randomization scheme called for an even 50/50 breakdown, there were 46 patients who received fascia and 54 who received polypropylene mesh. The reason for the discrepancy was that 4 patients randomized to receive fascia were actually given mesh because of a transient shortage of the Tutoplast material. A total of 89 patients (45 in the mesh group and 44 in the fascia group) returned for their 1-year follow-up visits. Figure 1 depicts a flow diagram of the enrollment and study period.

As expected with a randomized trial, there were no differences between the 2 groups with regard to preoperative POP-Q points, age, BMI, gravity, parity, race, prior prolapse or incontinence surgery, or hormone use (Table 1). Likewise, there were no demographic differences between the 100 study patients and the 101 patients who decided not to participate (Table 2).

There were no differences between the mesh and fascia groups with regard to perioperative characteristics such as estimated blood loss, surgical duration, and adverse events (Table 3). A separate analysis of these adverse events was performed to compare total number of potentially "graft-related" complications (namely, postoperative fever, ileus, wound breakdown, and graft erosions) per group. These "graft-related" complications occurred at a rate of 15% (7/46) in the fascia group and 26% in the mesh group ($P = .19$).

There was no difference between the 2 groups with respect to concomitant prolapse or incontinence procedures performed. Tension-free vaginal tape procedures were performed on 91% (42/46) of the fascia group and 87% (66%) of the mesh group ($P = .46$). Posterior repairs were performed on 43% (20/46) of the fascia group and 48% (26/54) of the mesh group ($P = .22$). Paravaginal repairs were performed on 70% (32/46) of the fascia group and 66% (36/54) of the mesh group ($P = .1$).

Of the 89 patients returning for their 1-year follow-up visits, 9% (4/45) of the mesh group and 32% (14/44) of the fascia group were classified as objective anatomic failures ($P = .007$). Of the 18 objective anatomic failures, 15 were classified as such because POP-Q point Aa reached the –1 position or beyond.

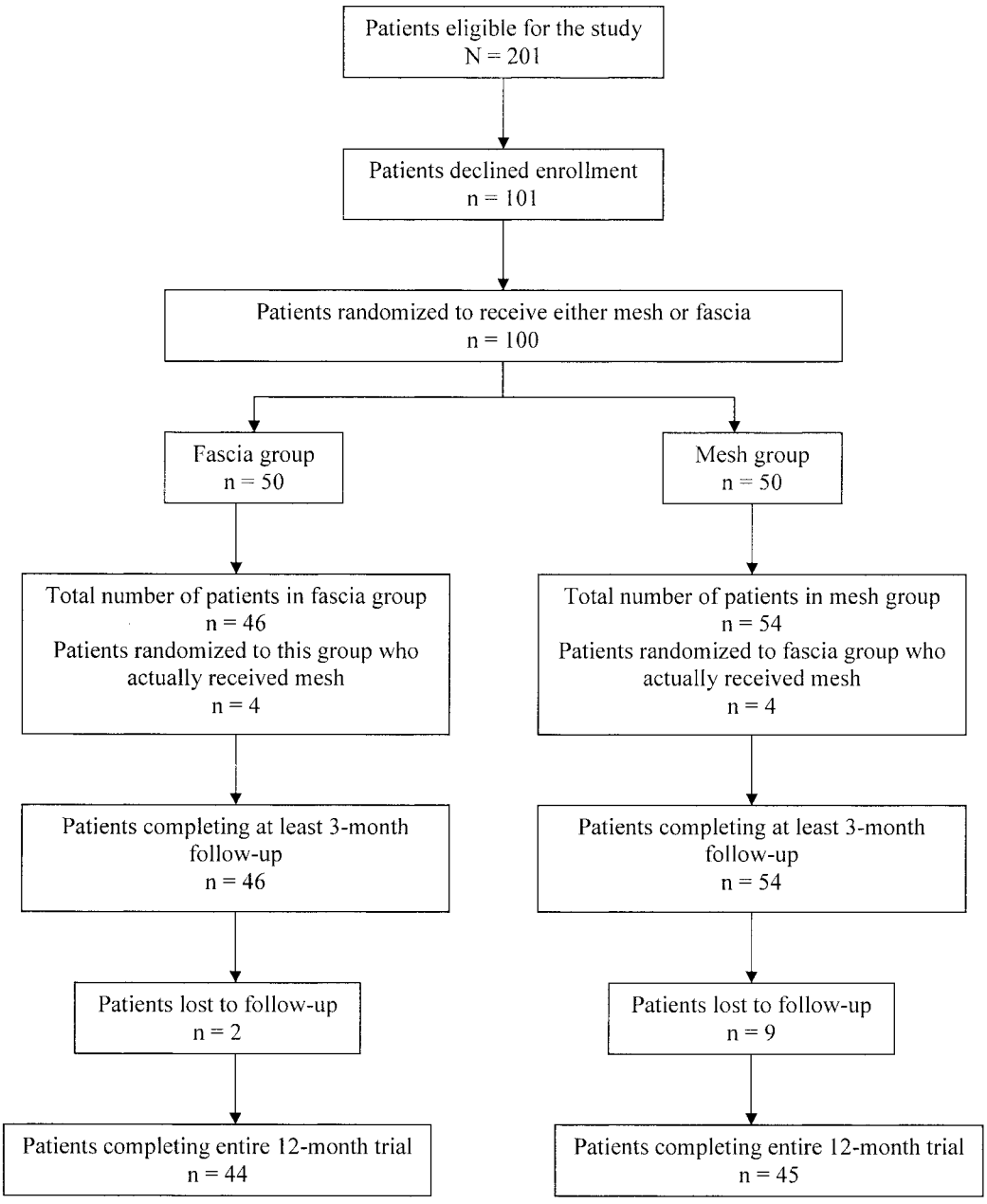

Fig. 1. A flow diagram of the enrollment and study period.
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The remaining 3 failures were classified as such because POP-Q point Ap reached the –1 point or beyond. There were no point C failures. In fact, the worst point C score found at the 1-year follow visit was –6. Four patients had that score (2 in fascia group and 2 in the mesh group).

We found significant differences between the mesh and fascia groups with respect to the 1-year postoperative comparisons of points Aa (ie, a point along the distal anterior vaginal wall), point C (the vaginal cuff), and POP-Q stage (Figs. 2–4). As shown in these figures, the means for each of these points changed differently between groups over time as well. The generalized estimating equation P values for POP-Q points Aa and POP-Q stage were .007 and $<$ .001, respectively. The means for point C (which was analyzed using Mixed Models Analysis) also changed differently between groups over time (P = .003). When compared both over time and at the last postoperative visit, there were no differences between the 2 groups with respect to POP-Q points TVL (total vaginal length), GH (genital hiatus), PB (perineal

Table 1. Preoperative Demographic Information for the Fascia and Mesh Groups

	Fascia (n = 46)	Mesh (n = 54)
Age (y)	57.5 ± 10.8	60.4 ± 10.1
Weight (lb)	158.8 ± 24.7	166.3 ± 31.3
Height (in)	64.0 ± 2.3	64.2 ± 2.6
Body mass index	27.3 ± 3.9	28.4 ± 4.7
Vaginal parity (median)*	2	3
Incontinence severity index	4.7 ± 3.9	4.5 ± 4.2
Preoperative Aa (cm)	0.1 ± 1.7	0.1 ± 1.8
Preoperative Ba (cm)	0.8 ± 2.5	0.9 ± 2.6
Preoperative C (cm)	–3.4 ± 3.1	–2.31 ± 5.3
Preoperative GH (cm)	3.7 ± 1.4	3.3 ± 1.2
Preoperative PB (cm)	3.6 ± 1.2	3.2 ± 1.0
Preoperative TVL (cm)	9.1 ± 1.2	9.1 ± 2.6
Preoperative Ap (cm)	–0.4 ± 1.8	–0.3 ± 2.1
Preoperative Bp (cm)	–0.1 ± 2.1	0.5 ± 2.9
Preoperative prolapse stage	2.4 ± 0.7	2.5 ± 0.5
Patients with ovaries present [% (n/n)]	56.5 (26/46)	50 (27/54)
Patients with prior continence or prolapse surgery [% (n/n)]	41.3 (19/46)	44.4 (24/54)

Aa and Ba, 2 points along the anterior vaginal wall; C, the vaginal cuff; GH, genital hiatus; PB, perineal body; TVL, total vaginal length; Ap and Bp, 2 points along the posterior vaginal wall.
Data are expressed as mean ± standard deviation except where otherwise indicated.
All *P* values are nonsignificant unless indicated (*).
* $P < .05$, because of one outlier in mesh group with a history of 10 vaginal deliveries.

body), and Ap or Bp (2 points along the posterior vaginal wall).

Other than graft material, we found no independent predictors of objective anatomic failure (defined as POP-Q stage ≥ 2). Univariate analyses were performed on variables potentially predictive of objective surgical failure. None of these variables, including age ($P = .96$), BMI ($P = .29$), prior prolapse or continence surgery ($P = .22$), achieved significance whether or not a given patient received a paravaginal repair along with her colpopexy ($P = .42$).

DISCUSSION

In terms of objective anatomic results (ie, POP-Q measurements), the synthetic mesh material proved superior to the cadaveric fascia lata. The objective anatomic failure rate among the patients receiving fascia was 32%, as opposed to a 9% failure rate in the

Table 2. Demographic Characteristics of the Total Study Group and Those Patients Who Declined Enrollment During the Study Period

	Eligible Patients Who Declined Enrollment (n = 101)	Total Number of Study Patients (n = 100)	*P* (n = 100)
Age (y)	61.0 ± 9.5	59.5 ± 10.5	.2
Body mass index	27.9 ± 4.9	27.9 ± 4.6	1.0
Preoperative Aa (cm)	0.1 ± 1.8	0.12 ± 1.8	1.0
Preoperative Ap (cm)	–0.3 ± 1.8	–0.2 ± 1.8	.9
Preoperative C (cm)	–2.5 ± 4.3	–2.8 ± 4.4	.6
Preoperative TVL (cm)	9.2 ± 2.5	9.1 ± 2.1	.7
Preoperative prolapse stage	2.3 ± 0.5	2.46 ± 0.64	.3
Vaginal parity (median)	3	3.08 ± 1.64	.7
Patients with prior prolapse or continence surgery [% (n/n)]	35.6 (36/101)	43 (43/100)	.3

Aa, a point along the anterior vaginal wall; Ap, a point along the posterior vaginal wall; C, the vaginal cuff; TVL, total vaginal length.
Data are expressed as mean ± standard deviation except where otherwise indicated.

Table 3. Perioperative Characteristics and Adverse Events Among Women in the Mesh and Fascia Groups

	Fascia (n = 46)	Mesh (n = 54)	*P*
Estimated blood loss (mL)	264.7 ± 261.4	247.2 ± 148.4	.68
Duration of surgery (min)	233.4 ± 66.9	227.3 ± 63.3	.40
Patients with postoperative fever	2	2	1.0
Patients with ileus	0	2	.5
Patients with wound breakdown	5	8	.8
Patients with erosion of graft	0	2	.5
Patients with intraoperative bladder injury	0	1	1.0
Patients requiring blood transfusion	0	1	1.0
Patients with postoperative pulmonary embolism	0	1	1.0

Data are expressed as mean ± standard deviation or number of patients.

mesh group (P = .007). That difference was not influenced by any other independent factors.

The vast majority of surgical failures occurred in the anterior compartment, which is consistent with many other reports[4] of the sacral colpopexy procedure. Interestingly, the performance of a paravaginal repair at the time of sacral colpopexy did not decrease the chance of objective anatomic failure in the anterior compartment.

This was the first randomized controlled trial comparing graft materials for use in the sacral colpopexy procedure. To make this determination, we conducted a MEDLINE search, using PubMed and Ovid, between the 1966 and February 2005. The following search terms were used to review all articles written in English: "sacral colpopexy," "sacropexy," "sacrocolpopexy," "colpopexy," "sacropexy," "colposacropexy," "abdominal sacrocolpopexy," "pelvic organ prolapse and surgery," and "vaginal vault prolapse and surgery." We then reviewed the Cochrane database for any randomized controlled trials regarding pelvic organ prolapse surgery.

The obvious strength of this study centers around the design. The randomization scheme minimized the chance of confounding by either measured or unmeasured variables. Both the study participants and the clinical research nurse (who collected all of the data) were blinded to the material used for each patient, which minimized the risk of ascertainment or information bias.

We specifically chose to study solvent-dehydrated cadaveric fascia lata because of previous experience with freeze-dried cadaveric fascia lata for pubovaginal slings,[20] which was similar to the experience of Fitzgerald et al[9–11] for sacral colpopexy. There is a small decrease in allograft strength caused by freezing

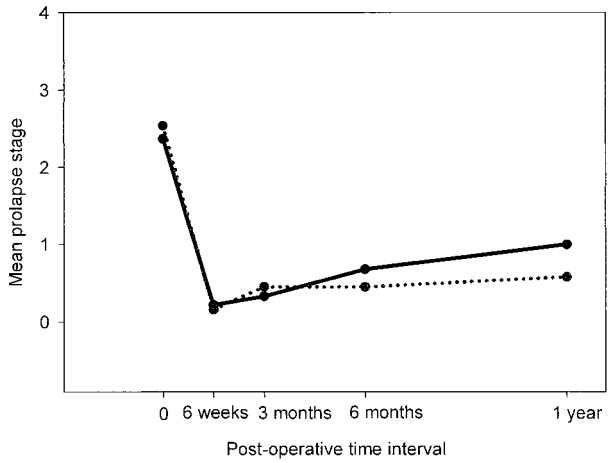

Fig. 2. Mean prolapse stage (based on POP-Q) graphed over 1 postoperative year for the mesh group *(dotted line)* and fascia group *(solid line)*. At 1 year, mean values were compared using the Mann-Whitney *U* test, P = .03. POP-Q, pelvic organ prolapse quantification system.

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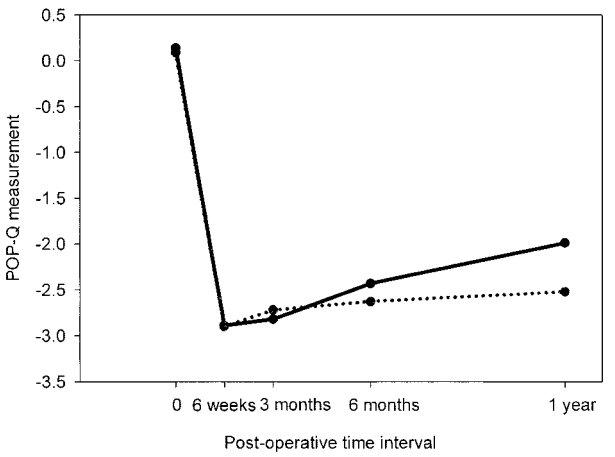

Fig. 3. Mean values of POP-Q point Aa graphed over 1 postoperative year for the mesh group *(dotted line)* and fascia group *(solid line)*. At 1 year, mean values were compared using the Mann-Whitney *U* test, P = .02. POP-Q, pelvic organ prolapse quantification system.

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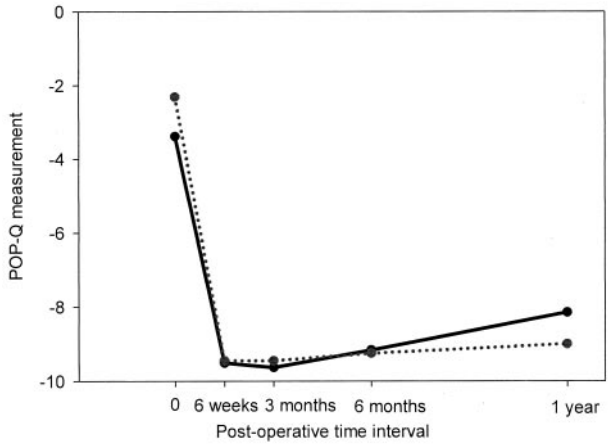

Fig. 4. Mean values of POP-Q point C graphed over 1 postoperative year for the mesh group *(dotted line)* and fascia group *(solid line)*. At 1 year, mean values were compared using the Mann-Whitney *U* test, $P = .04$. POP-Q, pelvic organ prolapse quantification system.

Culligan. Mesh Versus Fascia for Sacral Colpopexy. Obstet Gynecol 2005.

or freeze drying compared with chemical (solvent) dehydrated grafts. Hinton et al[21] showed that fascia lata allografts processed by solvent dehydration and gamma irradiation showed greater stiffness, maximum load to failure, and maximum load per unit width than their lyophilized counterparts. They hypothesized that lyophilization may cause subcellular ice crystal formation, which may adversely affect collagen microstructure, and concluded that a commercially available solvent-dehydrated form of fascia lata provides a more suitable grafting material than lyophilized specimens obtained from tissue banks.

The primary limitation of this study is the relatively short follow-up period of 12 months, which we chose based on our previously published sacral colpopexy case series.[6] In that report, we demonstrated that approximately 80% of the objective anatomic failures after sacral colpopexies occurred within 1 year. Although 5- to 10-year follow-up data would certainly be more compelling, such data always comes at the price of increased patient attrition. Our attrition rate of 11% after only 12 months illustrates the potential risks to validity when longer follow-up periods are chosen. Furthermore, the fact that we were able to demonstrate a significant difference between the 2 materials within a year proved that the 12-month study period was meaningful. In fact, we likely underestimated the true differences in objective anatomic failure, POP-Q prolapse stage, and POP-Q points Aa and C between the materials, because their graph lines were divergent at the end of the 12-month study period.

Another possible weakness of this study was the definition used for objective anatomic failure. We chose the strictest possible definition of surgical failure recommended by Weber et al,[12] namely, any postoperative POP-Q measurements of –1 or greater. Since that time, other authors[19–22] have suggested that a more lenient definition of objective anatomic failure (ie, including only those patients with prolapse beyond the hymen) may be more appropriate. Swift et al[23] interviewed and examined 497 women who required a pelvic examination and annual Pap test. He found a significant increase in the presence of the symptoms and their "bothersomeness" once the leading edge of their pelvic organ prolapse reached + 1 cm, as measured by the POP-Q system. Once the leading edge of the prolapse protruded beyond the hymenal remnants and the protection of the vaginal canal, the number of symptoms per subject more than doubled from 0.47 to 1.11.

In terms of an individual woman's quality of life, subjective outcomes are certainly more important than these definitions of objective anatomic failure. In other words, if a woman *feels* cured after prolapse surgery, then who is to tell her that she is wrong? As such, the subjective outcome measures collected as a part of this study may provide even more important insights than are presented in this report. In fact, comparing subjective outcome measures may even reveal a competitive advantage of solvent-dehydrated cadaveric fascial lata over synthetic mesh to support its continued use for sacral colpopexy. We have not yet completed the analyses of the subjective endpoints collected for this study. Nevertheless, our data suggest that the anatomic differences between patients who received cadaveric fascia lata and synthetic mesh will widen as time goes on.

In conclusion, we found polypropylene mesh to be superior to cadaveric fascia lata for use in sacral colpopexy with respect to objective anatomic failure rates, POP-Q points Aa and C, and POP-Q stage. Pelvic surgeons who decide to use polypropylene mesh should remain aware of the risk of vaginal mesh erosion at 1 year and beyond. That risk remains 4% or more[4] prompting our study group and others to continue the search for the "ideal" graft material.

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