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ORIGINAL ARTICLE

Randomized trial of fascia lata and polypropylene mesh for abdominal sacrocolpopexy: 5-year follow-up

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Abstract
Introduction and hypothesis The purpose of this study is to evaluate the 5-year surgical outcomes of abdominal sacrocolpopexy among subjects randomized to receive polypropylene mesh or cadaveric fascia lata.
Methods All 100 subjects from the original randomized clinical trial were eligible. Primary outcome was objective anatomic failure: any pelvic organ prolapse quantification (POP-Q) point ≥−1. Secondary outcome was clinical failure—presence of bulge or prolapse symptoms and either a POP-Q point C≥½ TVL or any POP-Q point >0—and interim surgical re-treatment. Wilcoxon tests and Fisher's exact test were performed.
Results Fifty-eight subjects returned for 5-year follow-up—29 mesh and 29 fascia. Objective anatomic success rates were: mesh, 93% (27/29) and fascia, 62% (18/29) (p=0.02). Clinical success rates were: mesh, 97% (28/29) and fascia, 90% (26/29) (p=0.61).
Conclusions Polypropylene mesh was superior to cadaveric fascia lata using objective anatomic outcomes. Success rates of mesh and fascia were comparable using a clinical definition that combined symptoms with anatomic measures.

Keywords Cadaveric fascia lata · Pelvic organ prolapse · Polypropylene mesh · Sacrocolpopexy · Vaginal vault prolapse

Introduction and hypothesis

Abdominal sacrocolpopexy performed with polypropylene mesh is considered the gold standard for surgical treatment of vaginal vault prolapse—based on objective anatomic outcome measures [1, 2]; however, objective anatomic measures (e.g., the pelvic organ prolapse quantification (POP-Q) scores) may not provide the true clinical picture after surgery.

The National Institutes of Health (NIH) workshop on standardization of terminology for researchers in pelvic floor disorders [2] recommended using the most conservative anatomic definition for researchers investigating the relationship between specific symptoms and various levels of prolapse as a first step toward developing a standardized definition. They recognized, and other researchers [3, 4] have confirmed, that many women's symptoms are relieved despite meeting an anatomic definition of failure. Combining anatomic criteria and subjective findings into a comprehensive definition of cure may be more clinically relevant [4, 5]. Barber et al. [5] found substantial variations in treatment success rates depending on whether the definition of success includes symptoms. They suggested

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that any definition of success should include the absence of prolapse at the level of the hymen, the absence of vaginal bulge symptoms, and the absence of re-treatment.

The report from the original randomized clinical trial [6] described a poor 1-year objective anatomic cure success rate among women who received cadaveric fascia lata compared with the success rate of women who received polypropylene mesh. No subjective findings were published for that trial. The primary aim of this study was to compare the objective anatomic success rates at 5 years of these original treatment groups. Our secondary aim was to use a "clinical" definition that combined subjective and objective components to compare the success rates between the treatment groups.

Materials and methods

The University of Louisville Human Studies Committee approved the initial double-blinded randomized study comparing polypropylene mesh and cadaveric fascia lata for sacrocolpopexy with 1-year follow-up. Eligible patients included women with post hysterectomy vaginal vault prolapse scheduled for abdominal sacrocolpopexy 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 abdominal sacrocolpopexy as the treatment for pelvic organ prolapse, each patient completed a separate informed consent process for the study itself. The University of Louisville Biomedical Institutional Review Board approved this 5-year follow-up study. All subjects who had participated in the initial randomized trial were eligible to participate in this 5-year follow-up study. Each subject in this study completed an additional informed consent process at the time of the 5-year follow-up visit.

As previously reported [6], a computerized blocked randomization scheme (using blocks of 8) was constructed to determine the type of material that would be used for the sacrocolpopexy. The master list for the randomization scheme was held by the statistician. The researchers received 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 surgery.

The mesh material used was polypropylene (Trelex; Boston Scientific, Boston, MA). The fascia used was solvent-dehydrated cadaveric fascia lata (Tutoplast processed Suspend fascia lata: Mentor Corporation, Santa Barbara, CA). Polytetrafluoroethylene sutures (CV-2 Gore-Tex, Gore, Flagstaff, AZ) were used to attach the graft material to the vagina and anterior longitudinal ligament overlying the sacrum.

Only the surgical team was aware of the subject's assignment to a graft type. Throughout the initial 1-year as well as the 5-year follow-up period, all preoperative and postoperative outcome measures for both studies were obtained by a single, masked, clinical research nurse (LB). The subjects were told by the surgeon which material they received after they completed the 1-year follow-up period. At the time of the 5-year follow-up visit, the subjects were asked not to reveal the type of graft material that had been used. Therefore, the clinical research nurse remained masked despite the fact that subjects were aware of their material type at the 5-year point. The principal investigator for the 5-year study (SBT) did not perform any of the original surgeries and was masked to the type of graft material used. At the end of the 5-year visit, the subjects were given a copy of the published report of the 1-year follow-up.

The clinical research nurse (LB) who recruited subjects for the original randomized trial recruited subjects for this study. Using the addresses on file, she sent a letter to all 100 subjects from the initial study inviting them to participate in a follow-up study. If there was a response, she set up an appointment or mailed questionnaires to those who were willing to complete them but could not come for a follow-up appointment. If there was no response and the letter was not returned, she made four more attempts to contact the subject over the course of a year. If there was no response but the letter was returned as undeliverable, she attempted to make contact through the emergency contact listed in the subject's medical record or through the referring physician. If those attempts failed, she checked telephone directories and used the internet to search for a current address. Recruitment began in September 2006 and ended in September 2008. Subjects were interviewed and examined in the offices of the Division of Urogynecology and Reconstructive Pelvic Surgery, Department of Obstetrics, Gynecology, & Women's Health at the University of Louisville Health Sciences Center. Subjects were compensated for their travel expenses and time.

During the intake interview at the 5-year follow-up visit, the research nurse asked the women to update their surgical history, medical conditions and medications. They were asked about subsequent prolapse or continence surgeries or adverse events since the 1-year follow-up visit. In addition, she administered the same validated questionnaires used in the initial study [6].

The clinical research nurse performed all the POP-Q measurements in the initial study—preoperatively at enrollment, and postoperatively at the 6-week and 3-, 6-, and 12-month visits—and performed those same measurements at the 5-year follow-up visit. The principal investigator (SBT) performed a vaginal examination on each subject to assess for graft erosion.

The primary outcome of interest in this study was the success of the two treatment groups at 5-year follow-up. We

used an objective anatomic definition of failure, POP-Q point≥−1 (≥stage 2). This same definition was used in the original study [6].

A secondary outcome of interest in this study was the effect on success of a definition that combined a subjective component, an anatomic component, and the need for surgical re-treatment of pelvic organ prolapse. This combined definition was used to represent a clinically relevant success.

To collect the subjective information, the clinical research nurse asked the subjects, "Do you have any symptoms of prolapse?" during the intake interview without elaboration and left to the subject's interpretation. A response of "yes" was considered positive. The other subjective measure was the subjects' response to question 9, on the Prolapse Symptom Inventory and Quality of Life Scale [7]. Question 9 reads, "I feel as though there is a 'ball' between my legs or that I am sitting on a 'ball'." A response of one of the following choices—all the time, most of the time, or some of the time—to question 9 was considered positive for "vaginal bulge". Subjects provided information about re-treatment during the 5-year follow-up intake interview.

The criteria for the anatomic component of the combined clinical definition were different from the criterion for the objective anatomic definition of the original study [6]. Based on findings of several studies [3, 4, 8–10] correlating symptoms and degree of pelvic organ support, the criteria consisted of any POP-Q point>0 or a POP-Q point C descending to halfway down the total vaginal length (TVL) or below. In addition to these anatomic criteria, a subject also had to have a subjective complaint of prolapse to be classified as a failure by the combined clinical definition. Based on the recommendations of Barber et al. [5], a subject was classified as a failure if she had had any surgical re-treatment of pelvic organ prolapse since the original surgery (Fig. 1).

Demographic and clinical characteristics of subjects who did and did not participate in this 5-year follow-up study were compared to identify potential sources of bias due to follow-up loss. Categorical variables were summarized with counts and percentages and compared between follow-up groups (e.g., followed at 5 years and not followed at 5 years) using Fisher's exact test. Ordinal and continuous variables were summarized with means and standard deviations and compared with Wilcoxon rank sum tests.

Demographic and clinical characteristics of the 5-year follow-up cohort were also summarized and compared between the polypropylene mesh and fascia lata groups. Measurements and stage classification from the POP-Q instrument at 1 and 5 years were summarized with means and standard deviations, and compared with Wilcoxon tests —signed rank tests for within-group comparisons and rank sum tests for between-group comparisons. All analyses were conducted using the open source R software package (R: A language and environment, The R Project for Statistical Computing, Vienna, Austria, http://www.r-project.org/).

Results

Fifty-eight of the 100 subjects (58%) returned for their 5-year visit—29/54 from the polypropylene mesh group and 29/46 from the fascia lata group. Eleven of the 100 subjects (11%) returned only questionnaires and therefore were not included in any of the analyses due to their lack of POP-Q examinations at 5 years. Thirty-one subjects did not respond, declined participation, and were lost to follow-up or had died of causes unrelated to the surgery. The follow-up rate did not significantly differ between treatment groups (Fisher's exact test, p=0.42).

The pre-operative and 1-year POP-Q scores and the changes from pre-operative to 1-year POP-Q scores did not significantly differ between subjects who were followed up at 5 years and those who were not. Thirty-three of 53 (62%) subjects with pre-operative POP-Q stage 2 prolapse returned for the 5-year follow-up and 22 of 41 (54%) with stage 3 prolapse. The rate of follow-up was not significantly different between these prolapse-stage groups (Fisher's exact test, p=0.53). The remaining pre-operative stage groups had negligible membership (one subject, stage 0; one subject, stage 1; and four subjects, stage 4). The subjects who did not return for the 5-year follow-up were slightly older (60± 12 years) than those who returned for follow-up (58± 9 years), but the difference was not significant (p=0.44). Among all subjects, those whose surgery was an anatomic success at 1 year were more likely to follow-up than year 1 anatomic failures; the difference in the follow-up rate was not significant (Fisher's exact test, p=0.79). This conclusion held in each of the treatment groups. Within the mesh treatment group, year 1 successes were not significantly more likely to follow-up than year 1 failures (p=0.32), although the small number of mesh failures at year 1 hindered this comparison. Within the fascia lata treatment group, year 1 successes were not significantly more likely to follow-up than year 1 failures (p=1.0). Additionally, year 1 fascia successes were not significantly more likely to follow-up than year 1 mesh successes (p=0.47), nor were year 1 fascia failures more likely to follow-up than year 1 mesh failures (p=0.28). This comparison, however, is on a very small subset of subjects. These observations provide evidence that the 5-year follow-up cohort was reasonably similar in demographic and clinical characteristics to the not-followed-up cohort, and alleviated concerns about non-response bias.

Comparisons of years 1 to 5 changes in POP-Q measurements and POP-Q stage within treatment groups

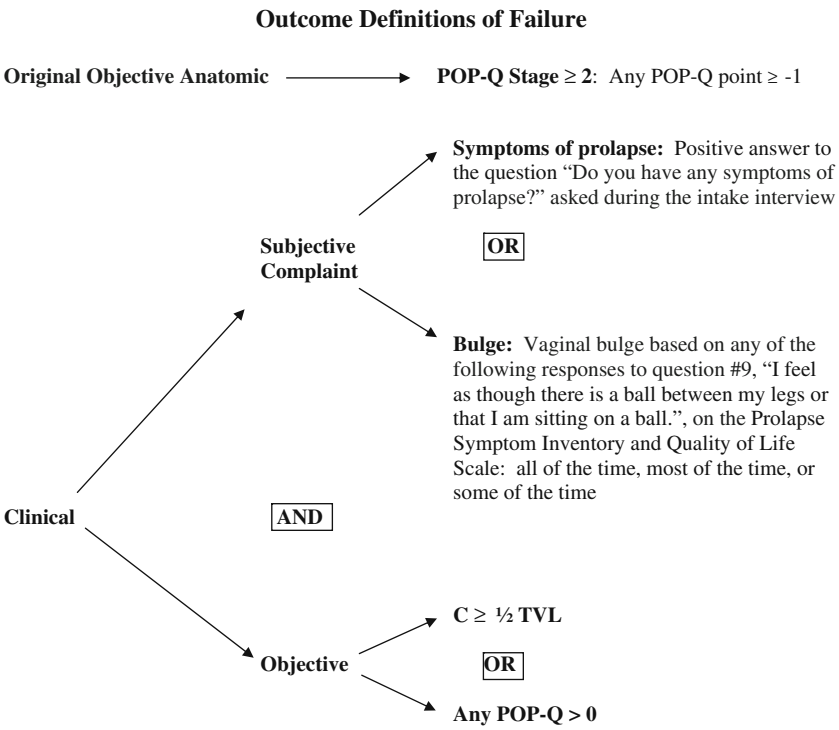

Fig. 1 The definitions used to measure outcomes at the 5-year follow-up visit

showed changes that reached statistical significance in TVL, C, and PB (Table 1); however, none of these was clinically significant. All other POP-Q measurements exhibited no significant change from years 1 to 5 within either group.

Comparisons of years 1 to 5 changes between treatment groups were all non-significant, indicating that neither group got significantly better nor significantly worse from years 1 to 5 in any POP-Q measurement or POP-Q stage (Table 1).

Success rates at the 1- and 5-year follow-ups using the objective anatomic definition and the success rates at the 5-year follow-up using the combined clinical definition are presented in Table 2. The 13 objective anatomic failures at 5 years were classified as such because either an anterior vaginal wall or a posterior vaginal wall POP-Q point reached the −1 position or beyond. There were no point C failures. The worst point C value found at the 5-year follow-up visit was −5.

Two of the four failures at 5 years were classified as such because they complained of vaginal bulge or prolapse symptoms and had at least one POP-Q point >0, and two subjects were classified as failures due to interim surgical re-treatment (Table 3).

Table 1 Mean ± SD POP-Q measurements and mean POP-Q stage at the 1- and 5-year visits and comparisons of changes in the means from years 1 to 5 within treatment groups and between treatment groups

POP-Q	Fascia			Mesh			Fascia vs Mesh
	1 year (n=46)	5 years (n=29)	P value[a]	1 year (n=54)	5 years (n=29)	P value[a]	P value[b]
Aa	−1.9±1.2	−1.8±1.5	0.87	−2.5±0.8	−2.6±0.7	0.40	0.66
Ba	−1.9±1.2	−1.8±1.5	0.95	−2.5±0.8	−2.6±0.7	0.19	0.46
C	−8.1±2.7	−7.8±1.4	0.01	−9±1.2	−8.1±1.4	0.0006	0.22
GH	2.4±0.7	2.5±0.7	0.51	2.3±0.6	2.4±0.8	0.95	0.42
PB	3.4±0.7	3.2±0.8	0.02	3.6±0.8	3.1±1	0.31	0.36
TVL	9.3±1	8.4±1.2	0.0007	9.4±1	8.5±1.1	0.0006	0.46
Ap	−2.7±0.6	−2.7±0.8	1.00	−2.9±0.3	−2.9±0.3	1.00	0.79
Bp	−2.7±0.6	−2.7±0.8	1.00	−2.9±0.3	−2.9±0.3	1.00	0.79
Stage	1±0.9	1±1	0.88	0.6±0.7	0.5±0.6	0.61	0.66

[a] Signed rank test for within treatment group comparisons

[b] Rank sum tests for treatment group comparisons

Table 2 Success rates at the 1- and 5-year follow-up visits by graft type and definition

Definition	1-year polypropylene mesh [6]	1-year cadaveric fascia [6]	*P* value	5-year polypropylene mesh	5-year cadaveric fascia	*P* value
Objective anatomic	41/45 (91%)	30/44 (68%)	0.007[a]	27/29 (93%)	18/29 (62%)	0.02[b]
Clinical	NA	NA		28/29 (97%)	26/29 (90%)	0.61[b]

NA not applicable

[a] *P* value is from Chi-square test

[b] *P* values are from Fisher's exact test

At 1-year follow-up, there were two graft erosions, one in each of the treatment groups. The polypropylene mesh erosion occurred at the posterior vaginal wall and eroded into the rectum. The removal of this polypropylene mesh required removal of a portion of bowel and a resulting colostomy. The subject transferred care and was lost to further follow-up. The subject whose fascia lata graft was eroded at 1-year follow-up did not follow-up between the 1- and the 5-year visits. At the 5-year visit, her fascial erosion remained, and she had developed postcoital spotting, dyspareunia, vaginal discharge, and odor. The subject underwent removal of the eroded portion of the graft without complications.

At the 5-year follow-up, there was one additional erosion in the polypropylene mesh group. This subject had a 2×3-cm apical polypropylene mesh erosion. A laparoscopic vaginal removal of the polypropylene mesh was performed and necrotizing fasciitis developed post-operatively at the umbilical port site. The subject experienced a prolonged hospitalization but recovered fully.

The two retreated subjects had documented cystocele repairs between the original surgery and the 5-year follow-up visit, one in the polypropylene mesh group and one in the fascia lata group. The latter's lowest anterior wall POP-Q point was 0 at 1 year. At 2 years, her lowest anterior POP-Q point was +3. Sometime between that 2-year exam and the 5-year follow-up, she had a cystocele repair at an outside institution. At the 5-year follow-up, she qualified as a failure by the objective anatomic definition but not by the clinical definition; however, she was included as a failure in our analysis because she was re-treated for pelvic organ prolapse. The subject in the polypropylene mesh group had persistent stress incontinence at the 6-month follow-up despite having had a tension-free transvaginal tape sling (TVT) with her sacrocolpopexy. She returned to surgery 8 months after the original procedure for a repeat TVT. Even though at the 6-month follow-up she answered "Never" to question 9 and her lowest anterior wall POP-Q point was 0, she had an anterior repair along with the repeat TVT. At the 5-year follow-up, she did not meet the criteria for either definition of failure; however she was included as a failure in the analysis because of interim surgical re-treatment.

Discussion

In this 5-year follow-up of a randomized trial comparing graft materials used in sacrocolpopexy procedures, we

Table 3 Subjects classified as failures at 5-year follow-up by objective anatomic and clinical definitions

Graft type	Fascia lata												Polypropylene mesh		
Subject no.	22	31	51	54	66	3	10	41	42	75	78	87	58	80	84
Subjective complaints															
Vaginal bulge	+	+	+		+										
Symptoms of prolapse		+	+		+										
Any POP-Q point>0		+		+	+										
POP-Q point C ½ TVL															
Surgical re-treatment							+								+
Failure by clinical definition[a]		+			+		+								+
Failure by objective anatomic definition[b]		+	+	+	+	+	+	+	+	+	+	+	+	+	

[a] Complaints of vaginal bulge or symptoms of prolapse and a POP-Q point>0 or POP-Q point C>½ TVL

[b] POP-Q point≥−1 (≥stage 2)

found that polypropylene mesh was superior to cadaveric fascia lata by the objective anatomic definition; however, when we used our combined clinical definition that included subjective as well as anatomic findings, there was no significant difference in the success rate of polypropylene mesh compared with that of cadaveric fascia lata. Fully 77% of those identified as failures by the objective anatomic definition were not symptomatic, lending credence to the notion that even less than perfect anatomical support may still reflect "cure" based on the patient's concept of "cure". The use of strictly anatomic outcome measures may overestimate prolapse. Therefore, women with asymptomatic anterior- or posterior-wall prolapse at −1 or 0 could be considered "normal", especially for parous women, as suggested by the NIH workshop report [2].

Since the publication of the NIH workshop report [2] that called for incorporating subjective findings in the definition of treatment success, subsequent studies [3, 4, 8–10] have correlated symptoms and the degree of pelvic organ support. Evidence continues to accumulate of the clinical usefulness of subjective measurements of success combined with anatomic criteria that correlate more closely with support. Recently, Barber et al. [5] documented the variation in 2-year success rates of abdominal sacrocolpopexy depending on the definition used to judge outcomes. Definitions that used strict anatomic criteria—optimal or satisfactory according to the NIH recommendations—produced success rates that were lower than those using less stringent anatomic criteria. Furthermore, including the absence of vaginal bulge symptoms seemed to be more clinically relevant than definitions of success that included only anatomic criteria. We found a similar effect when we used our combined clinical definition —objective anatomic criteria, less stringent and more closely correlated with degree of support than the objective anatomic criterion of the original study, and the absence of vaginal bulge symptoms.

The overall strength of this study adds weight to the implications of its findings. Our 5-year analysis is built on the rigor of the double-blinded randomized design of the original study. The 58 women who came back for objective and subjective assessments were statistically representative of the original study group. Having the same clinical research nurse for both studies and having the nurse and the principle investigator masked to graft type are additional factors. Finally, the findings of this study are furthered strengthened by the long-term follow-up of 5 years.

The results of this study call into question the dogmatic rejection of fascia lata as an appropriate graft material. In terms of anatomic support, the 1- to 5-year changes in the means of the POP-Q measurements did not reach statistical significance when compared between the two treatment groups. These results do not support the common belief that once "relaxation" starts, it will continue to progress becoming symptomatic and possibly requiring repeat surgery. At 5-year follow-up, the group was neither significantly better nor significantly worse than the other group in terms of pelvic organ support (Table 1). Furthermore, the combined clinical success rate of fascia lata seemed as good as that of polypropylene mesh.

In addition, the sequelae associated with polypropylene mesh erosions in this study were more serious than those associated with fascia lata. Two subjects with polypropylene mesh erosions developed serious complications associated with polypropylene mesh removal. One subject with a fascial erosion at the 1-year follow-up was asymptomatic and declined intervention. At the 5-year follow-up, she reported recent vaginal spotting, and removal of this fascial erosion was uncomplicated.

There are some limitations to our findings. A potential source of bias is the fact that the subjects were told by the surgeon at their 1-year follow-up visit which graft material was used in their surgery. This knowledge could have influenced their responses on the questionnaires and whether they reported symptoms at the 5-year follow-up visit. A copy of the published report of the 1-year follow-up study was given to them at the very end of the 5-year follow-up office visit. Unless the subjects had accessed the medical literature, they would not have known the findings regarding the superiority of the polypropylene material until after the 5-year visit.

A possible point of weakness is that we did not use a validated instrument to elicit information about subjective symptoms of prolapse for our combined clinical definition. We used questions that were indirect and did not specifically query the presence or absence of a bulge. Thus, it is possible that prolapse and bulge symptoms were underestimated in this study. At the time of study design, we hesitated to add additional questionnaires in our concern about questionnaire fatigue. Therefore, the same questionnaires used in the 1-year follow-up were administered at the 5-year follow-up visit. In retrospect, the addition of a validated prolapse symptom questionnaire such as the pelvic floor distress inventory [11] might have strengthened the results in that the questions regarding prolapse symptoms would have been direct and the presence of a bulge would have been specifically queried. In addition, there may be other subjective symptoms that, when added to vaginal bulge and prolapse symptoms, would more precisely identify poor anatomic support.

Overall, the results of this 5-year follow-up study of abdominal sacrocolpopexy show that, when using objective anatomic measures, polypropylene mesh is statistically better than cadaveric fascia lata; however, applying a measure that combines symptoms, anatomic findings, and surgical re-treatment produces comparable success rates for the two graft materials. Future research efforts regarding the success or failure of surgical treatment will be facilitated when there is consensus on a clinically relevant definition of pelvic organ prolapse.

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Conflicts of interest Susan B. Tate is a consultant and a paid instructor of C.R. Bard. Patrick J. Culligan is a consultant and a paid instructor of C.R. Bard, receives research support from Solace Therapeutics, receives research support from and is a consultant and paid instructor of Boston Scientific, and is a consultant and paid instructor of Intuitive Surgical.

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