A Pilot Study Comparing Anatomic Failure after Sacrocolpopexy with Absorbable or Permanent Sutures for Vaginal Mesh Attachment

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Abstract

Objectives: To describe anatomic failure rates for sacrocolpopexy in groups receiving either delayed absorbable or permanent monofilament suture for mesh attachment to the vagina.

Methods: We reviewed the medical records of 193 women who underwent sacrocolpopexy with 2 different types of sutures attaching polypropylene mesh to the vagina: delayed absorbable sutures (median follow-up, 43 weeks) and permanent sutures (median follow-up, 106 weeks). Vaginal apical failure was defined as Point C greater than or equal to half of the total vaginal length. Anterior-posterior compartmental failures were defined as Point Ba and/or Point Bp more than 0 cm. Fisher exact and χ^2 tests were used to compare failure rates. There were no documented suture erosions in the delayed absorbable monofilament suture group during the review period. Two patients in the permanent suture group were found to have permanent suture in the bladder more than 30 weeks after the index procedure.

Results: Failure rates for the 45 subjects in the delayed absorbable group and 148 subjects in the permanent suture group were similar (4.4% vs 3.4%, p = 0.74) and not statistically different in any compartment: apical (0% vs 1.4%, p = 0.43), anterior (4.4% vs 2%, p = 0.38), or posterior (0% vs 1.4%, p = 0.43).

Conclusions: Delayed absorbable monofilament suture appears to be a reasonable alternative to permanent suture for mesh attachment to the vagina during sacrocolpopexy. The use of delayed absorbable suture could potentially prevent complications of suture erosion into the bladder or vagina remote from the time of surgery.

Introduction

Sacrocolpopexy is a commonly performed technique for treating apical prolapse. Abdominal sacrocolpopexy was first described by Arthure and Savage[1] in 1957. The basic principles of sacrocolpopexy involve the attachment of a graft or mesh to the vagina while affixing the proximal end of the mesh to the anterior longitudinal ligament overlying the sacrum at levels S1 to S2. A recent comprehensive review of sacrocolpopexy and 7-year follow-up data from a randomized trial of sacrocolpopexy with or without Burch urethropexy describe a reoperation rate for prolapse of only 2.2% to 5.1%.[2,3]

Clinicians often use permanent suture to anchor the mesh to the vagina. Between our 2 institutions, during the previous 15 years, we are aware of at least 5 cases in which permanent monofilament suture has eroded into the bladder after sacrocolpopexy. These erosions presented many years after the index surgery despite the fact that intraoperative cystoscopic findings were noted to be normal.

Recent data suggest that permanent sutures may not be necessary. Porcine models demonstrate that 74% of the final strength of tissue ingrowth into polypropylene mesh is already achieved by 2 weeks after implantation, and maximum strength occurs by 3 months.[4] Delayed absorbable monofilament suture (polydioxanone or polyglyconate) loses 50% of its tensile strength by 4 weeks, 100% by 2 to 3 months, and complete mass absorption by 6 to 8 months.[5] In a recent large series of sacrocolpopexy vaginal erosions, 3 of 20 erosions were suture only.[6] Therefore, the use of absorbable sutures for mesh attachment during sacrocolpopexy is appealing because the risk of long-term suture exposure or knots eroding into the bladder would likely be eliminated. For these reasons, some of the surgeon authors (SAM and KML) began using delayed absorbable monofilament suture (polydioxanone [PDSII], Ethicon Inc, Somerville, NJ, or polyglyconate [Maxon], Covidien AG, Mansfield, MA) to attach, in 2008, Type 1 polypropylene mesh to the vagina.

The purpose of this study was to compare anatomic objective failure rates for minimally invasive sacrocolpopexy using delayed absorbable vs permanent monofilament suture for mesh attachment to the vagina. It was our hypothesis that the objective failure rates would not be significantly different between suture types because tissue ingrowth into mesh would occur by the time the delayed absorbable sutures lost their tensile strength.

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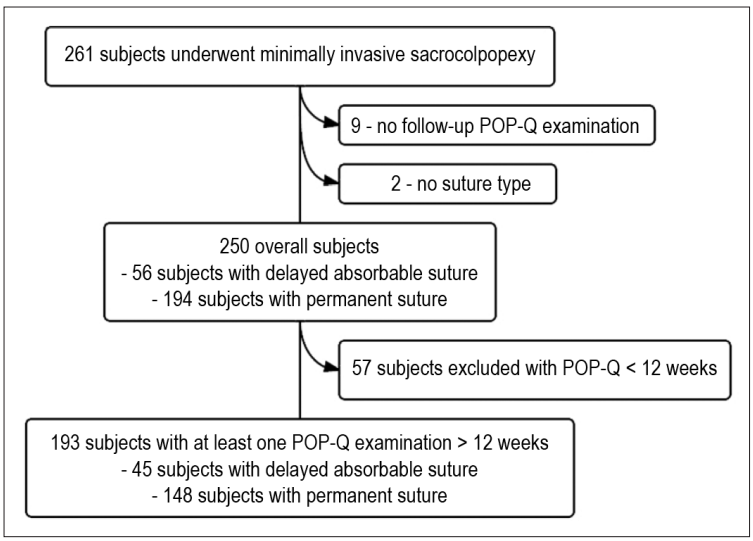

Figure 1. Enrollment of study subjects.
POP-Q = pelvic organ prolapse quantification.

Methods

This retrospective cohort study was approved by the institutional review board. The study included women who underwent minimally invasive sacrocolpopexy performed at the 2 institutions in our fellowship training program between November 2004 and January 2010. All subjects underwent sacrocolpopexy using either robotic-assisted laparoscopy or conventional laparoscopy. Details of our operative procedure have been published.[7] In brief summary, our technique consisted of anterior and posterior leaflets of polypropylene mesh with at least 6 sutures placed on each leaflet to secure the mesh to the vaginal surface. Inclusion criteria were as follows: 1) operative report documentation of delayed absorbable monofilament (polydioxanone or polyglyconate) or permanent monofilament (polypropylene) sutures for mesh attachment to the vagina and 2) at least 1 follow-up visit with a pelvic organ prolapse quantification[8] performed 12 weeks or more after surgery.

Data were extracted from the electronic medical record and hospital charts. Demographic data and baseline and postoperative pelvic organ prolapse quantification measures were collected from eligible subjects. Operative techniques and complications were abstracted from the hospital records. Postoperative follow-up visits, including pelvic organ prolapse quantification and the detection of suture complications, were also documented.

Our primary outcome was objective apical failure defined as Point C greater than or equal to half of the total vaginal length and/or objective failure of the anterior and posterior

Table 1. Demographic data

Demographic variable	Delayed absorbable sutures, n = 45	Permanent sutures, n = 148	p value
Mean age ± SD (years)	60 ± 9	61 ± 9	0.854[a]
Median (range) follow-up duration, in weeks	43 (12-272)	106 (12-372)	0.007[b]
Median (range) time to failure for primary or secondary outcomes, in weeks	58 (55-61)	6 (5-181)	0.143[b]
Median preoperative stage of prolapse (mean)	3 (3.0)	3 (2.8)	0.002[b]
Concomitant surgery, no. (%)			
Procedure for repair of pelvic organ prolapse	16 (36.0)	38 (26.0)	0.196[c]
Anterior colporrhaphy	0 (0)	8 (5.1)	0.336[c]
Posterior colporrhaphy	13 (29.0)	28 (18.9)	0.152[c]
Paravaginal repair	5 (11.1)	12 (8.1)	0.534[c]
Hysterectomy	32 (71.9)	61 (41.2)	0.001[c]

[a] Student *t* test.
[b] Nonparametric testing.
[c] Chi-squared test.
SD = standard deviation.

compartments, which we defined as Point Ba and/or Point Bp more than 0 cm. We performed analysis using this definition of prolapse because it appears to be the most appropriate definition for surgical success. Barber et al[9] suggested that beyond the hymen might correlate more highly with subjective symptoms of surgical failure. This definition was used in the large randomized trial of sacrocolpopexy (Colpopexy and Urinary Reduction Efforts, or CARE), whose results were published in 2013.[3]

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The records of subjects who were determined to have anatomic failures were further reviewed. Data were abstracted whether the patients reported being asymptomatic, being symptomatic but declining surgery, or if they underwent repeated operation for prolapse.

Chi squared tests and Fisher exact tests were used to evaluate dichotomous variables; Student's *t* test was used for continuous, normally distributed data; and Wilcoxon rank tests were used to compare nonparametric variables. Odds ratios (ORs) and 95% confidence intervals (CIs) are reported. A p value of less than 0.05 was considered statistically significant. Statistical analysis was performed with PASW Statistics 18 (IBM, Armonk, NY).

Results

A total of 261 women underwent minimally invasive sacrocolpopexy at our institutions during the study period, and 74% had sufficient data to be included in the analysis (Figure 1). Of the 26% who were not included in the study, there were no significant differences in age, parity, body mass index, or preoperative stage of prolapse between the subjects included in the analysis (data not shown). Of those included, there were no differences in mean age, median follow-up duration (or range), median (or range) time to failure for primary or secondary outcomes, or rates of concomitant surgery for pelvic organ prolapse between the delayed absorbable and permanent suture groups (Table 1). On nonparametric testing, the delayed absorbable group had statistically but not clinically worse preoperative stage compared with the permanent suture group.

The anatomic objective failure rates for the different suture groups were similar and not statistically different for the participants with at least 12 weeks of follow-up (Table 2). No difference was seen in the objective failure rates in the robotic surgery group (3.4%, n = 2) vs the laparoscopic surgery group (3.7%, n = 5).

Of the 7 overall subjects with anatomic failure at the hymen or beyond, 3 (43%) were asymptomatic, 3 (43%) were symptomatic but declined reoperation (with 1 of them using a pessary), and 1 (14%) was scheduled for reoperation. The subject planning reoperation with an anterior colporrhaphy was in the permanent suture group.

There were no documented suture erosions in the delayed absorbable monofilament suture group during the review period. Two patients in the permanent suture group were later found to have permanent suture in the bladder. One patient presented at 47 weeks after her surgery with urinary frequency and nocturia. She was noted to have microscopic hematuria and underwent cystoscopy, revealing a suture in the bladder, which was removed cystoscopically. Urinary symptoms subsequently improved. The second patient presented 32 weeks after surgery with large-volume urinary leakage, which developed only immediately before presentation. She was noted to have a vesicovaginal fistula with polypropylene (Prolene) suture and mesh visible in the bladder. Two patients were noted to have polypropylene suture in the vagina remotely after surgery at postoperative weeks 30 and 279.

Vaginal mesh erosion rates were 17% in the permanent suture group and 13% in the delayed absorbable suture group, a difference that was not statistically significant (p = 0.385). Concomitant hysterectomy was performed in 41% of the permanent suture group and 72% of the delayed absorbable suture group (p = 0.001). There was a significant difference in the mesh erosion rate among participants receiving a concurrent hysterectomy vs the subjects who did not undergo a hysterectomy at the time of sacrocolpopexy (23% vs 10%, p = 0.014).

Discussion

In this preliminary analysis of the use of delayed absorbable monofilament suture (polydioxanone or polyglyconate) to secure polypropylene mesh to the vagina, apical failure rates were low, and we did not identify increases in objective failure rates compared with permanent monofilament suture in patients with more than 12 weeks of follow-up. On the basis of these data and the biochemical properties of the delayed absorbable suture, we believe that there is sufficient tissue ingrowth into the polypropylene mesh during the period of adequate suture tensile strength to prevent failure.

Table 2. Anatomic failures

Anatomic failure	Delayed absorbable sutures, n = 45, no. (%)	Permanent sutures, n = 148, no. (%)	Odds ratio (95% CI)	p value
Overall failure by definition	2 (4.4)	5 (3.4)	1.33 (0.25-7.10)	0.738
Apical point (C ≥ half of total vaginal length)	0 (0)	2 (1.4)[a]	—	0.433
Anterior compartment point (Ba > 0 cm)	2 (4.4)	3 (2.0)[a]	2.2 (0.36-13.80)	0.376[b]
Posterior compartment point (Bp > 0 cm)	0 (0)	2 (1.4)[a]	—	0.433[b]

[a] Three subjects in the permanent sutures group and 0 subjects in the delayed absorbable sutures group with simultaneous multicompartment failure.
[b] Fisher exact test.
CI = confidence interval.

The choice of sutures and mesh material used during pelvic reconstruction is an important one. In a study of sacrospinous ligament suspensions, braided polyester permanent suture had an unacceptably high rate (36%) of suture-related complications such as suture erosion, persistent granulation tissue, and persistent vaginal bleeding that required suture removal in 70% of cases.[10] Sacrocolpopexies with expanded polytetrafluoroethylene (Gore-Tex, WL Gore and Associates, Flagstaff, AZ) mesh were associated with a 4-fold higher risk of erosion, and most clinicians have opted not to use this material in their practices.[6]

Permanent monofilament suture has been widely used for securing mesh to the vagina during the sacrocolpopexy procedure. The rationale for the use of permanent suture is to secure the mesh to provide a durable repair with a theoretical lower rate of failure than that with absorbable suture. Vaginal suture erosions are often considered less morbid than mesh erosions; however, the etiology of vaginal mesh erosion is not completely understood, especially in the absence of a colpotomy. It has been postulated that if the sutures that secure the mesh to the vagina traverse the full thickness of the vagina, vaginal bacteria may travel along the suture to colonize the mesh.[6] If this theory is true, the presence of permanent suture securing the mesh to vagina places patients at risk of erosion, even many years after surgery. We observed 2 permanent suture erosions into the bladder occurring more than 30 weeks after surgery.

There is very limited literature comparing the use of monofilament absorbable suture vs permanent suture when mesh is attached to the vagina. One study by Maher et al[11] compared laparoscopic sacrocolpopexy with vaginal mesh-reinforced repairs. The laparoscopic sacrocolpopexy subjects (n = 53) had their mesh attached to the vagina using delayed absorbable monofilament suture and had a 77% objective success rate after 6-month follow-up. The study did not compare success rates for absorbable vs permanent sutures.[11] One retrospective abdominal sacrocolpopexy study comparing the use of braided, permanent, polyester sutures (2-0 Ethibond Excel, Ethicon, Somerville, NJ) with monofilament delayed absorbable (2-0 polydioxanone, Ethicon) in mesh attachment to the vagina found that the use of monofilament absorbable suture appeared to reduce the risk of graft-suture erosion without increasing surgical failure.[12] However, their study was limited by only 20% of patients having follow-up greater than 6 weeks. Our results confirm these short-term results, but also confirm the durability of the delayed absorbable monofilament suture technique after suture absorption.

Even more bothersome and more morbid than vaginal suture erosions are erosions of foreign material into the bladder. The presence of permanent suture in the bladder many years after sacrocolpopexy prompted 2 of the surgeons at our institution to begin using delayed absorbable sutures for mesh attachment to the vagina. In the cases involving permanent suture in the bladder, those women had normal cystoscopy results at the time of their sacrocolpopexy. We attribute the high rate of vaginal mesh erosions noted in this cohort to the high rate of concomitant hysterectomy (48%) overall. On the basis of a previous publication, we have determined that there is a 6-fold increase in vaginal mesh erosion when associated with hysterectomy.[13] We noted a significant difference in the mesh erosion rate between patients receiving a concurrent hysterectomy (23%) and those who did not (10%).

Even though our absorbable mesh group had slightly worse preoperative median prolapse, which should have biased this group to more failures, this was not observed. Most of the failures were in the anterior and posterior compartments, which may not be related at all to surgical failure since these more distal compartments may not have received adequate support from the sacrocolpopexy.

The strengths of this study are its moderately large sample size, inclusion of 74% of subjects, use of the standardized pelvic organ prolapse quantification, a contemporaneous study period, and the long follow-up duration.

Limitations of this study are primarily related to its retrospective nature and nonstandardized follow-up intervals. This study took place at two institutions with seven different surgeons performing these procedures. All surgeons are fellowship-trained urogynecologists. There was substantial overlap in the study period, with permanent suture being used from 2004 to 2010, whereas the delayed absorbable suture was used by two of the seven surgeons from 2008 to 2010. More patients in the delayed absorbable suture group had a hysterectomy at the time of surgery, and this could potentially influence the results. Two different surgical modalities were used for the sacrocolpopexy, although there was no difference in failure rates between the robotic and laparoscopic groups. A further limitation of our study is that our results were purely objective, and we do not have reliable subjective symptoms for the anatomic success group. Subjective data were specifically collected from the patients if their operation failed.

Conclusion

We consider delayed absorbable polydioxanone or polyglyconate suture to be a reasonable alternative to permanent monofilament sutures to potentially prevent complications of suture erosion into the bladder or vagina remote from surgery. The findings from this study should be further confirmed in a randomized trial of delayed absorbable vs permanent suture. ❖

Disclosure Statement

Drs Tan-Kim, Menefee, Lippmann, Luber, and Nager have no relevant financial disclosures. Dr Lukacz is a consultant for Pfizer, Inc, a Scientific Medical Advisor for Med Edicus, and an Advisory Committee member for AMS. She receives grant support from Boston Scientific and the National Institutes of Health.

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Knowing

It is impossible to know perfectly the part, if one is not acquainted with the whole, even in a gross way (grosso modo); so it is impossible to be a good surgeon if one is not familiar with the foundations and generalizations of medicine. On the other hand, as it is impossible to know the whole perfectly if we are not acquainted in a certain measure with each of its parts, it is impossible for anyone to be a good physician who is absolutely ignorant of the art of surgery, with a knowledge of its possibilities and its limitations.

— *Cyrurgia,* Henri de Mondeville, 1260-1316, the "Father of French Surgery"