

The effect of suture material on outcomes of surgery for pelvic organ prolapse

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Abstract: **OBJECTIVE.** To evaluate the effect of using different suture material on outcomes of surgery for pelvic organ prolapse. **METHODS.** This was a retrospective cohort study of all patients having undergone surgery for pelvic organ prolapse from February 1997 to June 2003. All subjects underwent a comprehensive evaluation with ensuing surgery for pelvic organ prolapse. **RESULTS.** Of the 505 cases of surgery for prolapse, information on suture material was available on 423 procedures (83.8%). Poly L-lactide/glycolide (Panacryl®) was found to have the highest incidence of granulation tissue/infection (53.3%/13.3%) followed by polybutylate-coated polyester (Ethibond®) (26.3%/10.3%), polypropylene (Prolene®) (10.9%/4.5%), and polydioxanone (PDS®) (3.8%/2.5%). These differences were significant ($p < 0.05$). Granulation tissue was more common with vaginal surgery than other routes (19.8% vs. 7.4%), although the difference was not significant. While the overall incidence of recurrent prolapse was 33.9% (all stages) with 3.2% having stage 3 or 4 prolapse, only 9.9% required additional surgery for prolapse and/or incontinence. There was no significant difference in recurrence of prolapse or repeat surgery rates among the different suture materials. **CONCLUSIONS.** Braided sutures such as polyester and poly-L-lactide/glycolide had a much higher incidence of suture-related complications requiring treatment than monofilament sutures, making monofilament suture preferable in vaginal surgery.

Key words: Suture material; Prolapse surgery; Complications.

INTRODUCTION

Surgery for pelvic organ prolapse (POP) is very common with 11% of women requiring surgery at least once in their life.¹ With dozens of different procedures being performed and more being developed all the time, attempts are being made to find the most durable procedure. Unfortunately failure rates can be as high as 63% after surgery for prolapse.²

While most studies investigating surgical outcomes have focused on studying the actual procedures, there is very little information assessing technique. The choice of suture material used in vaginal reconstruction can be as critical as the procedure itself. The selection of suture material has often been at the discretion of the operating surgeon with little scientific evidence to guide the selection. Recently there has been a trend towards increased use of permanent suture in reconstructive pelvic surgery.

The goal of this study is to determine whether surgical outcomes differ when using different suture material.

MATERIALS AND METHODS

Data was collected retrospectively from the office charts of patients having undergone surgery for POP from February 1997 to December 2003. The Institutional Review Board of the Louisiana State University Health Sciences Center granted approval for the study. A systematic audit of all patient charts had been performed for review in a previously published article.³ This database was queried for patients who met the inclusion criteria.

Patients were included if they underwent surgery for POP during the indicated time frame. Patients were excluded if they only underwent anti-incontinence surgery. Data collected included demographic and background data, including previous surgical history. The initial visit, operative report and all post-operative visits were reviewed.

Outcome variables included recurrence of prolapse, recurrence of incontinence and the incidence of additional surgery for prolapse or incontinence. Recurrent prolapse was defined as any descent of any compartment of the vagina below the normal anatomic position (greater than stage zero by the Baden-Walker Halfway system⁴). Recurrent inconti-

nence was defined as any subjective incontinence recorded in the chart during the post-operative visits. Patients requiring additional surgery for POP or incontinence were only tracked if they followed up with the two primary surgeons (NF and RRC). Patients who left the practice were not followed.

Secondary outcome variables include suture-related complications including the incidence of granulation tissue persisting or occurring beyond the first six post-operative weeks, the incidence of post-operative vaginal infection defined as antibiotic use for vaginal discharge, and the need for surgical treatment for these complications. Follow up interval was defined as the time interval (months) from surgery to the last post-operative visit. In the case of those patients who had additional surgery, the follow up interval was defined as the time from initial surgery to the second surgery.

Cases were excluded from analysis if the suture material was not documented or if the operative report was not available. Additionally, cases in which infrequently-used suture material (less than 5 cases), were excluded from analysis. Patients were also excluded if the follow up interval was less than three months.

Data was recorded in a paper database before compiling them centrally into a computer database (Microsoft Access®, Microsoft Corp., Redmond, WA). Statistical analysis was performed using SPSS 11.0 for Windows (SPSS Inc., Chicago, IL). Student t-test and ANOVA were used to compare means for continuous variables. Chi-square was used to compare categorical data. Fisher's exact test was performed when the assumptions for the Chi-square distribution were violated. The Mann-Whitney U-test was used to compare means when normality assumptions were violated. Logistic regression was used to create both univariate and multivariate models. A p-value < 0.05 was considered significant.

RESULTS

Of the 502 cases occurring during this time frame with adequate follow up, information on suture material was available on 401 patients. The demographic data for this sample is described in Table 1, comparing braided suture

TABLE 1. – Demographic data.

Category	Braided (n=223)	Monofilament (n=178)	Significance
Age (years)	61.6	61.7	NS
BMI (kg/m ²)	26.8	26.1	NS
Gravidity	3.5	3.6	NS
Parity	3.0	3.0	NS
Race (%)			<.05
– Caucasian	159 (71.3%)	127 (71.3%)	
– Black	12 (5.4%)	1 (0.6%)	
– Hispanic	6 (2.7%)	7 (3.9%)	
– Unknown	46 (20.6%)	43 (24.2%)	
Previous hysterectomy	176 (78.9%)	128 (72.7%)	NS
Prior reconstructive surgery	90 (40.4%)	67 (37.9%)	NS
Tobacco use (n=393)	24 (10.8%)	12 (7.0%)	NS
Menopausal (n=390)	179 (81.4%)	139 (81.8%)	NS
– If menopausal, % on HRT (n=312)	126 (72.4%)	98 (71.0%)	NS
Concurrent anti-incontinence surgery	176 (78.9%)	84 (47.2%)	< 0.001
Concurrent graft use	65 (29.3%)	46 (25.8%)	NS
Vaginal route	206 (92.4%)	166 (93.3%)	NS
Procedures			
– USLS	103 (46.2%)	94 (52.8%)	NS
– ASC	6 (2.7%)	4 (2.2%)	NS
– Posterior repair	42 (18.8%)	47 (26.4%)	NS
– Perineorrhaphy	52 (23.3%)	15 (8.4%)	<0.001
– Other	20 (9%)	18 (10%)	NS
Follow up interval (months)	13.3	8.3	< 0.001

NS = not statistically significant.

to monofilaments. The median follow up interval was 7 months with a range of 3-67 months. The patient's pre-operative stage of prolapse was not statistically different.

There were four different brands of suture material

TABLE 2. – Comparison of different materials.

Outcome	Poly-L-Lactide/ Glycolide (Panacryl®) (n = 13)	Coated Polyester Polyester (Ethibond®) (n = 210)	Polypropylene (Prolene®) (n = 132)	Polydioxanone (PDS®) (n = 46)	Significance
Recurrent prolapse	2 (15.4%)	70 (33.3%)	50 (37.9%)	17 (37.0%)	NS
Recurrent urinary incontinence	3 (23.1%)	55 (26.2%)	29 (22.0%)	8 (17.4%)	NS
Further surgery for prolapse	0	19 (9.0%)	7 (5.3%)	4 (8.7%)	NS
Post-operative complications					
Granulation/ suture erosion	6 (46.2%)	56 (26.7%)	20 (15.2%)	2 (4.3%)	<0.001
Infection	1 (7.7%)	22 (10.5%)	6 (4.5%)	0	<.05
Interval from surgery (months)	3.5	5.0	6.0	7.0	NS
Management of complications (n=78)					
Cautery	2 (100%)	29 (50.9%)	9 (45.0%)	1 (50.0%)	NS
Cut suture	0	16 (28.1%)	7 (35.0%)	1 (50.0%)	NS
Surgery	0	11 (19.6%)	2 (10.0%)	0	NS

NS = not statistically significant.

included in the analysis. These sutures were the following: 1) coated polyester (Ethibond®; n = 210), a braided, permanent suture, 2) polypropylene (Prolene®; n = 132), a monofilament, permanent suture, 3) polydioxanone (PDS®; n = 46), a monofilament, delayed-absorbable suture, and 4) poly-L-lactide/glycolide (Panacryl®; n=13), a braided, very delayed-absorbable suture. Outcome measures for each of these materials are listed in Table 2.

For the purpose of analysis, these sutures were then grouped into braided and monofilament sutures. Comparisons are listed in Table 3. There was no difference in the main surgical outcome variables such as recurrent prolapse, recurrent incontinence and additional surgery. Braided sutures were more likely than monofilaments to lead to suture-related complications such as granulation tissue (27.8% vs. 12.4%; p < 0.001) and vaginal infection (10.3% vs. 3.4%; p = 0.008).

Table 4 shows the results when comparing the absorbable to the permanent sutures. As shown in the chart there is no difference with regards to surgical outcomes or complications.

Regression analysis was then performed to identify and control for all factors that could contribute to post-operative granulation tissue and infection. For each outcome, univariate analysis was used to identify those individual variables that showed a significant association. These variables were then all used to build a complete model. Using a stepwise, backward method of analysis, insignificant variables were removed from the model until all variables in the model were considered significant. The results of both the univariate analysis and the multivariate analysis for both outcomes (granulation and infection) are listed in Table 5. With regards to granulation tissue, braided suture and graft use were independent risk factors (r = 0.367). Braided suture was a risk factor after controlling for graft use [O.R. 2.777, 95% CI 1.604-4.808]. With regards to infection, braided suture, graft use and black race were independent risk factors (r=0.492). Braided suture associated with infection [OR 3.236, 95% CI 1.022-10.243] after controlling for graft use and race were also independent risk factors.

DISCUSSION

Surgical correction for pelvic organ prolapse is very common today. It is anticipated that the need for treatment of prolapse will increase dramatically over the ensuing dec-

TABLE 3. – Braided suture vs. monofilament.

Category	Braided (n=223)	Monofilament (n=178)	Significance
Recurrent prolapse	72 (32.3%)	67 (37.6%)	NS
Recurrent stage 3 prolapse	8 (3.6%)	4 (2.2%)	NS
Recurrent urinary incontinence	58 (26.0%)	37 (20.8%)	NS
Further surgery for prolapse	19 (8.5%)	11 (6.2%)	NS
<i>Post-operative complications</i>			
Granulation/ suture erosion	62 (27.8%)	22 (12.4%)	<0.001
Infection	23 (10.3%)	6 (3.4%)	<.05
Interval from surgery (months)	4.8	6.1	NS
<i>Management of complications (n=78)</i>			
Cautery	29 (46.8%)	10 (45.5%)	NS
Cut suture	16 (25.8%)	8 (36.4%)	NS
Surgery	11 (17.7%)	2 (9.1%)	NS

NS = not statistically significant.

TABLE 4. – Absorbable vs. Permanent suture.

Category	Absorbable (n=59)	Permanent (n=342)	Significance
Recurrent prolapse	19 (32.2%)	120 (35.1%)	NS
Recurrent urinary incontinence	11 (18.6%)	84 (24.6%)	NS
Further surgery for prolapse	4 (6.8%)	26 (7.6%)	NS
Further surgery for prolapse or incontinence	4 (6.8%)	41 (12.0%)	NS
<i>Post-operative complications</i>			
Granulation/ suture erosion	8 (13.6%)	76 (22.2%)	NS
Infection	1 (1.7%)	28 (8.2%)	NS
Interval from surgery (months)	4.4	5.3	NS
<i>Management of complications (n=78)</i>			
Cautery	2 (25.0%)	37 (48.7%)	NS
Cut suture	1 (12.5%)	23 (30.3%)	NS
Surgery	0	13 (17.1%)	NS

NS = not statistically significant.

TABLE 5. – Univariate and multivariate analysis using granulation as primary endpoint.

Variable	GRANULATION		INFECTION	
	Odds ratio	95% CI	Odds ratio	95% CI
<i>Univariate</i>				
Graft use	3.351	2.025-5.544	4.891	2.229-10.734
Braided suture	2.731	1.601-4.657	3.297	1.312-8.283
Age > 70	0.527	0.294-0.946	0.578	0.228-1.465
Follow up > 12 months	2.066	1.246-3.428	3.013	1.403-6.474
Black race	4.492	1.456-13.860	9.757	2.896-32.875
Perineorrhaphy	0.670	0.367-1.226	0.410	0.178-0.946
<i>Multivariate</i>				
	r=0.367		r=0.492	
Graft use	3.382	2.020-5.664	6.835	2.582-18.094
Braided suture	2.777	1.604-4.808	3.236	1.022-10.243
Black race	NS		7.736	1.926-31.067

ades. To identify the optimal surgical procedure to meet this future demand, surgeons have begun to analyze the way prolapse is corrected. Examples of this include studying the route of surgery, the use of graft to augment surgery and comparison of the different procedures.

Luck et al. compared permanent braided suture to absorbable braided suture in patients undergoing site specific posterior repairs. They found 31% suture erosion in the polyester (Ethibond®) group compared to 9% in the polyglactin group (Vicryl®). Their findings for polyester (Ethibond®) were similar to the findings of this study; however they did not include permanent or delayed absorbable monofilament suture.⁵

One possible explanation why monofilament suture may be less reactive in the vagina relates to the structure of the suture. Braided sutures may permit bacteria to adhere to the individual filaments within the interstices of the suture whereas monofilament suture does not have any such sites to harbor bacteria. Bacteria trapped within the weave of a suture may be difficult for macrophages to access for eradication, leading to chronic granulation and infection.

Suture selection has historically been at the discretion of the surgeon. Although certain characteristics have importance, such as handling, durability, permanence versus absorbability, and training bias, the most common reason a suture is chosen is personal experience.⁶ In an attempt to overcome this bias, this trial provides some comparative data.

This study has confirmed what many surgeons have anecdotally noted. Braided suture was more prone to post-operative complications such as granulation and infection.⁷⁻⁹ Panacryl was the most likely suture material to cause complications. Recently this material has been withdrawn from the market secondary to chronic inflammatory complications as described here.

Braided polyester has become a preferred suture by many reconstructive surgeons, because of its knot security and ease of handling. The data presented here provides an argument for an alternative in vaginal surgery. With polypropylene having an equivalent success rate to polyester with a diminished complication rate, monofilament suture has become preferable in our practice. Polypropylene ties very easily with secure knots when square throws are used. The main concern involves suture erosion resulting in a stiff knot that might cause a sharp sensation to the phallus during intercourse. That complication has been avoided with modifications to the surgical technique which bury the knot further.

In this series monofilament suture has a lower complication rate. As previously discussed, braided sutures may harbor bacteria within the interstices of the suture causing a host reaction to the bacteria within the suture. Monofilaments avoid that potential source of infection. Alternatively biomechanical properties of the suture material might also play a role. Examples of these properties include the tensile strength, reactivity or elasticity. Unfortunately while there is a great deal of data analyzing tensile strength, there is little information regarding the response of vaginal tissue to suture material.

There are several limitations to this study. First, the retrospective design limits the conclusions that can be drawn. Controlling for the reasons that different sutures were selected would eliminate one potential source of bias. It was impossible to extrapolate the rationale for suture selection from a retrospective chart review. Recall and recording biases could have affected the results. The short follow up interval only allowed short-term outcomes to be assessed. This study only analyzes vaginal reconstructive cases. A similar assessment of abdominal and/or laparoscopic cases is also warranted.

The ideal study would eliminate selection bias by randomizing patients for all surgeons. A single surgical technique using only select sutures would be ideal. The POP-Q and validated prolapse questionnaires are more reliable measures of outcomes. Longer follow up is necessary. Using a well-designed protocol, the optimal suture material could hopefully be identified.

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There was no financial support from industry or otherwise for this project.

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