

DELAYED ABSORBABLE MONOFILAMENT SUTURE FOR MESH ATTACHMENT TO THE VAGINA WITH SACROCOLPOPEXY.

Hypothesis / aims of study

The sacrocolpopexy is a highly effective technique for treating apical prolapse. The vast majority of clinicians use permanent suture to anchor the mesh to the vagina; but some recent data suggest that permanent sutures may not be necessary. Porcine models demonstrate that 74% of the final strength of tissue in-growth into polypropylene mesh is already achieved by 2 weeks postoperatively and maximum strength occurs by 3 months [1]. Delayed absorbable monofilament suture (polydioxanone or polyglyconate) loses 50% of its tensile strength by 4 weeks, 100% by 2-3 months with complete mass absorption by 6-8 months [2]. In a recent large series of sacrocolpopexy erosions, 3 of 20 erosions were suture only [3]. Sometimes these suture knots can erode into the bladder. With the use of absorbable sutures for vaginal mesh attachment, the risk of long term vaginal suture exposure or knots eroding into the bladder is eliminated. For these reasons, some of us (SAM and KML) began using delayed absorbable monofilament suture (polydioxanone - PDSII™, Ethicon, Inc., Somerville, NJ, USA or polyglyconate – Maxon™, Covidien AG, Mansfield, MA, USA) to attach type 1 polypropylene mesh to the vagina in 2008.

The purpose of this study is to compare objective failure rates for minimally invasive sacrocolpopexy (MISC) using delayed absorbable versus permanent monofilament suture for mesh attachment to the vagina. It is our hypothesis that the objective failure rates will not be significantly different between suture types because tissue in-growth into mesh has occurred by the time the delayed absorbable sutures lose their tensile strength.

Study design, materials and methods

This was an IRB approved, retrospective cohort study of women who underwent MISC performed at the two institutions in our fellowship-training program between 11/04 and 7/09. All subjects either underwent a robotic assisted laparoscopic sacrocolpopexy or a conventional laparoscopic sacrocolpopexy. Inclusion criteria were: 1) documentation of delayed absorbable monofilament (polydioxanone or polyglyconate) or permanent monofilament (polypropylene) sutures for mesh attachment to the vagina, 2) sacrocolpopexy performed at least 6 months prior to the review, 3) at least one follow-up visit with a POPQ examination performed 4 weeks or more after surgery. Our primary outcome was objective apical failure defined as point C > -½ total vaginal length. Our secondary outcome was anterior and posterior compartment objective failure which we defined as point Ba and/or Bp ≥ 0.

Chart review captured demographic data, baseline POPQ, and post operative POPQ measures on eligible subjects. Chi-square tests and Fisher's exact tests were used to evaluate dichotomous variables, student's t test for continuous, normally distributed data and Wilcoxon rank tests were used to compare non-parametric variables. Odds ratios (OR) and 95% confidence intervals (CI) are reported. A p-value of <0.05 was considered statistically significant. Statistical analysis was performed with PASW 18 (SPSS, Inc, Chicago, IL).

We based our power analysis on the assumption that a 20% difference in objective apical failure rate would be clinically significant given that traditional ASC techniques have an approximate 5% failure rate. Knowing we had 28 subjects in the delayed absorbable suture group we calculated that an allocation ratio of 6 (168 permanent suture subjects) would detect a 20% difference in objective failure rate (5 vs. 25%) with $\alpha=0.05$ and 80% power.

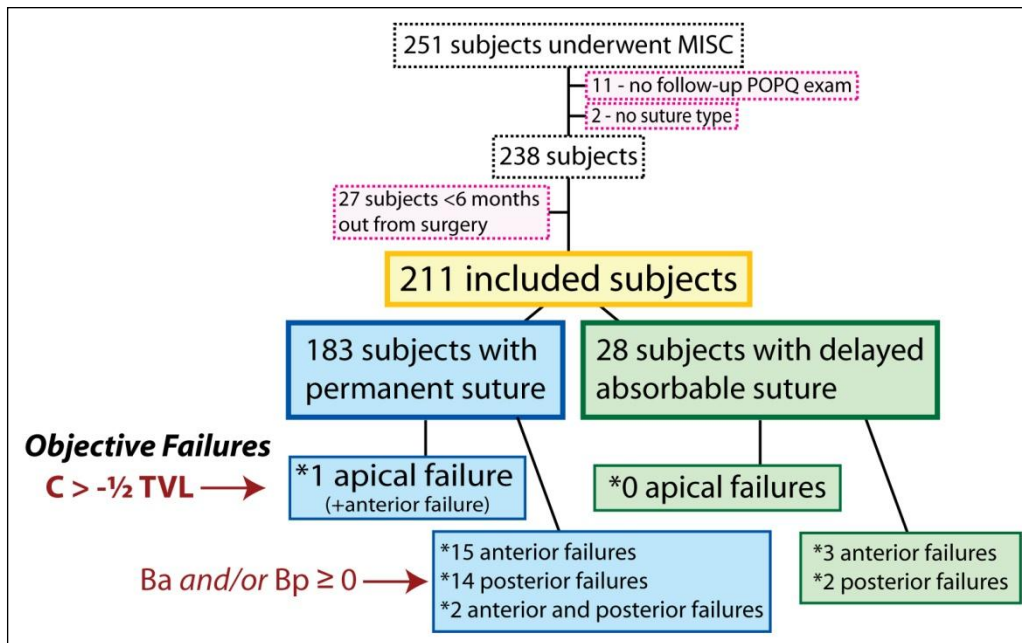
Results

A total of 251 women underwent MISC at our institutions since 11/04 and 84% had sufficient data to be included in the analysis (Figure 1). There were no differences in mean age (60 ± 8 vs. 60 ± 9 years, $p=0.64$), median preoperative prolapse stage (stage 3 vs. stage 3, $p=0.14$), median [range] follow-up duration (21 [4-171] vs. 16 [5-62] weeks, $p=0.61$) or median [range] time to failure for primary or secondary outcomes (27 [4-130] vs. 56 [13-62] weeks, $p=0.38$) between the permanent and delayed absorbable suture groups.

There was 1 apical failure in the permanent suture group and 0 in the delayed absorbable group resulting in a 0.5% (1/211) overall apical failure rate (OR 0.995, 95%CI 0.984-1.005, $p=1.00$). The objective failure rates including apical, anterior, and posterior prolapse as defined by our primary and secondary outcomes were similar: 17.4% (32/183) for our permanent suture group and 17.8% (5/28) for our delayed absorbable group (OR 1.026, 95%CI 0.363-2.901, $p=0.96$). The permanent suture group and delayed absorbable group also had similar rates of anterior (11% vs. 10%, $p=0.75$) and posterior prolapse (9% vs. 7%, $p=1.0$). There was no correlation between age ($p=0.759$) or preoperative POPQ stage ($p=0.108$) and the presence of objective failure in any compartment.

Of the 37 subjects who met criteria for objective failure, 31 (84%) were at the hymen (0 cm), and only 6 (16%) were beyond the hymen (>0 cm). Of the 37 subjects: 30 (81%) were asymptomatic, 3 (8%) underwent reoperation, 2 (5%) were symptomatic but declined reoperation and 2 (5%) were considering surgery. All three subjects who underwent reoperation were in the permanent suture group; two had anterior repairs and one had a posterior repair.

Figure 1.



Further analysis was performed to determine if there was a difference in short term (<6 months) objective failure rates in any compartment. The short term failure rate was a 7% (13/183) in the permanent suture group and 8% (2/28) in the delayed absorbable group (p = 0.99).

Interpretation of results

In this preliminary study, the use of delayed absorbable monofilament suture (polydioxanone or polyglyconate) to secure polypropylene mesh to the vagina did not increase objective failure rates. These similar failure rates were observed regardless of whether we used a strict definition of apical failure or a more relaxed definition of mostly asymptomatic anterior and posterior failures. We think there is sufficient tissue in-growth into the polypropylene mesh during the time period of adequate suture tensile strength to prevent failure. Although we recommend that this pilot data be confirmed in larger scale trials, we consider delayed absorbable polydioxanone or polyglyconate suture to be a reasonable alternative to prevent complications of permanent suture, such as suture erosion into bladder or vagina remote from surgery.

Concluding message

Our preliminary results suggest that the use of a delayed absorbable monofilament (polydioxanone or polyglyconate) suture does not result in a different objective failure rate when compared to permanent polypropylene suture for the attachment of mesh to the vagina during sacrocolpopexy.

References

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| Was the Declaration of Helsinki followed? | Yes |
| Was informed consent obtained from the patients? | No |