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ORIGINAL ARTICLE

Long-term mesh exposure after minimally invasive total hysterectomy and sacrocolpopexy

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Abstract

Introduction and hypothesis The objective was to evaluate total and incident mesh exposure rates at least 2 years after minimally invasive total hysterectomy and sacrocolpopexy. Secondary aims were to evaluate surgical success and late adverse events.

Methods This extension study included women previously enrolled in the multicenter randomized trial of permanent vs delayed-absorbable suture with lightweight mesh for ≥ stage II uterovaginal prolapse. Owing to COVID-19, women were given the option of an in-person (questionnaires and examination) or telephone visit (questionnaires only). The primary outcome was total and incident suture or mesh exposure, or symptoms suggestive of mesh exposure in women without an examination. Secondary outcomes were surgical success, which was defined as no subjective bulge, no prolapse beyond the hymen, and no pelvic organ prolapse retreatment, and adverse events.

Results A total of 182 out of 200 previously randomized participants were eligible for inclusion, of whom 106 (58%) women (78 in-person and 28 via questionnaire only) agreed to the extension study. At a mean of 3.9 years post-surgery, the rate of mesh or suture exposure was 7.7% (14 out of 182) of whom only 2 were incident cases reported after 1-year follow-up. None reported vaginal bleeding or discharge, dyspareunia, or penile dyspareunia. Surgical success was 93 out of 106 (87.7%): 13 out of 94 (13.8%) failed by bulge symptoms, 2 out of 78 (2.6%) by prolapse beyond the hymen, 1 out of 85 (1.2%) by retreatment with pessary, and 0 by retreatment with surgery. There were no serious adverse events.

Conclusions The rate of incident mesh exposure between 1 and 3.9 years post-surgery was low, success rates remained high, and there were no delayed serious adverse events.

Keywords Sacrocolpopexy · Mesh exposure · Total hysterectomy · Outcomes

Introduction

Sacrocolpopexy (SCP) is often considered the gold standard treatment for the management of apical prolapse [1] and is increasingly employed as a treatment strategy for women with uterovaginal prolapse [2]. Vaginal mesh exposure is the most commonly identified mesh complication of SCP, yet prevalence rates vary widely depending on type of synthetic mesh material [3, 4], length of follow up [5], concomitant total hysterectomy [6–8], smoking [9], and use of permanent braided suture material for graft attachment [10]. Although total hysterectomy is associated with increased mesh exposure, it confers the advantages of a lower risk of recurrent anterior wall prolapse, elimination of risk of future cervical pathological conditions and vaginal bleeding from retained endometrial tissue, and transvaginal tissue extraction without morcellation [11].

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In 2020, we reported the results of the Permanent versus delayed-Absorbable Monofilament Suture for Vaginal Graft Attachment during Minimally-Invasive During Total Hysterectomy and Sacrocolpopexy Randomized Control Trial (PACT), in which 200 women with advanced, primary uterovaginal prolapse underwent total hysterectomy and SCP using a lightweight polypropylene mesh and were randomized to permanent versus absorbable suture for vaginal mesh attachment [12]. At 1-year post-surgery, the overall rate of mesh exposure was 6.1%, with no difference between suture groups, and 94% of women met a composite definition of success.

Despite the growing popularity of minimally invasive SCP as a primary intervention for uterovaginal prolapse, there is a paucity of long-term data regarding efficacy and risk, particularly of mesh-related complications [13]. In fact, the extended-CARE trial is the only prospective long-term study that evaluated outcomes at a mean of 7 years post-surgery and reported a 10.5% risk of mesh exposure [5]. That study has poor applicability to current practice as participants underwent laparotomy and less than one third had a type 1 polypropylene mesh, none of which were lightweight. In addition, the majority of cases did not have concomitant total hysterectomy, a known risk factor for mesh exposure.

The purpose of this extension cohort study, therefore, was to evaluate longer-term mesh exposure, surgical efficacy and late complications in women who underwent minimally invasive total hysterectomy and SCP, and determine if suture type for vaginal graft attachment influenced results. The results of the study will provide important information to women considering a primary total hysterectomy and SCP for advanced uterovaginal prolapse.

Materials and methods

The E-PACT is an extension study of the previously reported PACT study [12] that was conducted at the same five clinical sites as the original trial, which enrolled patients between April 2015 and May 2019: Wake Forest Baptist Health, University of North Carolina, Northwestern Memorial Health Care, Augusta University, and Atrium Health. The primary aim of the original trial was to compare vaginal mesh or permanent suture exposure rates in women undergoing minimally invasive total hysterectomy (robotic or laparoscopic) and SCP with a lightweight polypropylene mesh using permanent (2–0 polytetrafluoroethylene, Gore-Tex) versus delayed absorbable monofilament (2–0 polydioxanone, PDS) sutures within 1-year postoperatively. The primary aim of this extension trial was to evaluate prevalent and incident mesh exposure and associated symptoms for the entire cohort. Mesh exposure was defined as "vaginal mesh visualized through separated vaginal epithelium" according to the IUGA/ICS joint classification system [14]. Secondary aims included surgical failure with either a report of a bothersome bulge they could see or feel as per the Pelvic Floor Distress Inventory (PFDI-20) [15] question 3, response of 2 or higher (i.e., responses of "somewhat," "moderately," or "quite a bit" of bother), objective prolapse recurrence beyond the vaginal introitus or retreatment with a pessary or surgery, and whether suture type influenced these longer-term results.

All participants previously enrolled in PACT who had not voluntarily withdrawn from the primary study were eligible to participate once they were at least 24 months post-procedure. Institutional Review Board approval was obtained at each clinical site. We attempted to contact all patients via telephone, electronic mail, text message, and certified mail to offer enrollment in this extension study. Owing to the limitations associated with in-person assessments during the COVID-19 pandemic, patients were offered the option of an in-person visit with questionnaires and pelvic examination versus remote assessment of symptoms only via questionnaires. All patients provided written informed consent prior to participation. Any patient with a previous diagnosis of mesh or permanent suture exposure was carried forward as a mesh exposure regardless of whether they could be contacted for participation in this extension study.

Patients who elected for a remote assessment (symptom-only group) were required to complete the Pelvic Floor Distress Inventory-20 [15], Patients Global Impression of Improvement (PGI-I) [16], and the Pelvic Organ Prolapse Incontinence Sexual Questionnaire-IUGA Revised [17], to assess symptom bother, improvement, and sexual functioning respectively. Additionally, investigators inquired about symptoms suggestive of mesh exposure including vaginal bleeding, discharge, pelvic pain, and partner perception of vaginal mesh exposure. Interim adverse events, including any prior assessment or treatment for mesh exposure was obtained via electronic medical record review. No physical examinations were conducted in this group. Once the study team received the completed questionnaires from remote patients, patients were sent a Visa Clincard for compensation.

For women who agreed to an in-person assessment, the same questions and validated questionnaires were administered followed by a physical examination, Pelvic Organ Prolapse Quantification (POP-Q) System assessment [18], and a pelvic examination (including speculum and bimanual examination) to evaluate for permanent suture or mesh exposure, pelvic organ prolapse symptoms, granulation tissue, pelvic pain, vaginal discharge, and vaginal bleeding. Interim adverse events were recorded through direct patient query and review of the electronic medical record. All postoperative protocol-defined adverse events (new and persistent) were classified according to the Clavien–Dindo grading

scale [19] and filed in the patient's chart. Patients were compensated at the completion of the study visit.

All data were entered into a secure database, REDcap, by the research staff at the end of each visit. Study data were monitored for the entire duration of the trial. Statistical analysis was performed using SPSS version 25 (IBM, Armonk, NY, USA). Means and standard deviations or counts and percentages were computed for univariate analyses using continuous and categorical data respectively. Student's *t* test, Chi-squared test, or Fisher's exact test were used for bivariate analyses. A p value < 0.05 was considered statistically significant.

Results

Based on the original study of 200 participants, 182 were eligible for inclusion, of whom 106 (58%) agreed to participate (78 in-person and 28 via questionnaire only). Mean follow-up after index surgery for this extension trial was 3.9 ± 0.9 years. Demographic characteristics are presented in Table 1. Overall, the majority of participants were postmenopausal, non-Hispanic white, overweight, and nonsmokers. Almost half of participants underwent a mesh mid-urethral sling (45%) and rectocele repair (46%). There were no significant differences in demographic or surgical data between women who agreed to enrollment in the study versus those who declined.

For our primary outcome, we assessed the rate of total and incident mesh or permanent suture exposure. The rate of mesh or suture exposure at the time of follow-up was 5.7% (6 out of 106), including 6 participants with mesh exposure and 0 participants with permanent suture exposure. The 6 participants with mesh exposure included 5 in the in-person group (documented on examination) and 1 in the questionnaire-only group (reported by the participant from a previous office examination). There were no cases reported on the basis of patient symptoms only. There was no significant difference in mean age or follow-up time for women with and without an examination. In comparison, there were 13 cases of mesh or permanent suture exposure in the original PACT study at any time up to 1 year follow-up, for a mesh and suture carry forward exposure rate of 7.1% (13 out of 182). This included 10 participants with mesh exposure, 2 with mesh and permanent suture, and 1 with permanent suture exposure only.

Table 1 Patient characteristics

Characteristics	All participants (*N*=106)
Age (years)	60.4 ± 9.4
Race	
White	95 (89.6)
African American	10 (9.4)
Native Hawaiian	1 (0.9)
Ethnicity	
Non-Hispanic	95 (89.6)
Hispanic	11 (10.4)
BMI (kg/m^2)	28.9 ± 5.7
Smoking status	
Never	72 (67.9)
Prior smoker	11 (10.4)
Current smoker	2 (1.9)
Concurrent sling	48 (45.3)

Data presented as n ± SD or n (%)

When assessing the evolution of mesh and permanent suture exposure from PACT to E-PACT, we found that of the 13 original participants, 8 did not follow up for E-PACT, including both women with mesh and permanent suture exposure and those with the suture-only exposure. Among those who did follow up for E-PACT, 4 continued to have mesh exposure. In addition to these continuing participants, 2 new participants with mesh exposure were documented, for a total prevalence rate of mesh exposure at any time post-surgery of 7.7% (14 out of 182). There were no new participants with suture exposure in the current follow-up study, for a carry forward rate of 1.1% (2 out of 182). In terms of location, 4 of the mesh exposures were on the posterior vaginal wall, 1 was on the anterior vaginal wall, and 1 was apical. All of the mesh exposures were at the site of the SCP mesh and none were attributed to sling mesh exposure.

Regarding tobacco use, 5 of the participants with mesh exposure were never smokers and 1 was a prior smoker. Mean BMI was 32.6 in the mesh exposure group, with only 1 participant having a BMI < 30. Mesh and permanent suture exposures were managed as follows: 4 (66.7%) vaginal estrogen, 2 (33.3%) office trimming, and 1 (16.7%) vaginal mesh excision surgery. For women without a study visit, there was one reported participant with mesh exposure, who was treated with office trimming. None of the participants with mesh exposure reported vaginal bleeding or discharge, dyspareunia, or penile dyspareunia.

Our secondary aims were to evaluate surgical success and late adverse events. Surgical success was 93 out of 106 (87.7%) based on any of the following criteria: 13 out of 94 (13.8%) failed by bulge symptoms, 2 out of 78 (2.6%) by prolapse beyond the hymen, 1 out of 85 (1.2%) by retreatment with pessary, and 0 by retreatment with surgery. There were no differences in these outcomes based on suture group (permanent vs absorbable, Table 2). When assessing pelvic floor function based on validated questionnaires, overall function was good. Mean PFDI score was 120 ± 125, mean Pelvic Floor Impact Questionnaire (PFIQ) score was 0.3 ± 0.5, and mean PGI-I score was 1.3 ± 0.8. The absorbable

Table 2 Patient outcomes

Characteristics	Permanent suture (n=57)	Delayed absorbable suture (n=49)	p value
Current POP-Q stage			
Stage 0–I	26 (45.3)	26 (53.1)	0.46*
Stage II	12 (21.1)	7 (14.3)	
Stage III	3 (5.3	3 (6.1)	
Stage IV	1 (1.8)	0 (0)	
No examination	15 (26.3)	13 (26.5)	
Surgical failure	9 (15.8)	4 (8.2)	0.26**
Sexually active at follow-up	17 (56.1)	16 (59.2)	0.63**
Sexually active at baseline	32 (56.1)	29 (59.2)	0.84**
PFDI	142 ± 138	96 ± 106	0.04***
PFIQ	0.4 ± 0.5	0.3 ± 0.5	0.21***
PGI-I	1.2 ± 6.3	1.5 ± 1.0	0.08***

Surgical failure defined as bulge symptoms, prolapse beyond hymen, or retreatment with pessary or surgery

Data presented as n ± SD or n (%)

POP-Q Pelvic Organ Prolapse Quantification, *PFDI* Pelvic Floor Distress Inventory, *PFIQ* Pelvic Floor Impact Questionnaire, *PGI-I* Patients Global Impression of Improvement

* Fisher's exact test

** Pearson Chi-squared test

***Student's t test

Table 3 Adverse events

Characteristics	All participants (n=106)
Any adverse event	36 (34.0)
Mesh exposure at ≥2-year visit	6 (5.7)
Granulation tissue	1 (0.9)
Vaginal atrophy	16 (15.1)
Pelvic pain	
Mild	9 (8.5)
Moderate	1 (0.9)
Severe	0 (0)
Baseline pain	12 (11.3)
Dyspareunia	5 (4.7)
Abdominal pain	2 (1.9)
Vaginal bleeding	3 (2.8)
Vaginal discharge	3 (2.8)
Stress incontinence	31 (29.2)
Urge incontinence	32 (30.2)
Urinary tract infection	3 (2.8)
Constipation	2 (1.9)

Data presented as n ± SD or n (%)

suture group demonstrated less bother based on PFDI score than the permanent suture group. There were no differences in PFIQ or PGI-I scores (Table 2). When assessing adverse events, only 34 (32%) participants reported an adverse event. The most common were vaginal atrophy (16), pelvic or vaginal pain (7), dyspareunia (5), recurrent urinary tract infection (3), vaginal bleeding (3), and vaginal discharge (3). There were no delayed serious adverse events (Table 3).

Discussion

In this longitudinal cohort study with a mean follow-up of almost 4 years post-minimally invasive total hysterectomy and SCP using a lightweight polypropylene y-mesh, we demonstrate a very low rate of new incident mesh exposure (2 cases, 1.8%), no cases of permanent suture exposure, and an absence of any associated bothersome symptoms of vaginal discharge, bleeding, or pain. There was only 1 case of mesh exposure that required surgical excision of the exposed mesh in the operating room, which occurred during the first year of follow-up. The remaining cases were managed with transvaginal estrogen or office trimming. Carrying cases of mesh exposure forward that were diagnosed within the first year postoperatively, the overall prevalence of mesh exposure was 7.7%. This is considerably lower than was demonstrated in the extended-CARE trial [5] despite 100% of PACT participants undergoing total hysterectomy, a known risk factor for mesh exposure. We attribute our findings to the use of a lightweight, type 1 polypropylene mesh material. Our results are comparable with several other studies in which a similar mesh material was used [20, 21], although none studied a homogenous group that all underwent minimally invasive total hysterectomy [13]. The suture type for vaginal graft attachment did not affect our long-term mesh exposure rates. A factor that likely impacts mesh exposure is the method of vaginal cuff closure. This was not standardized in the original trial as no evidence-based method was deemed superior for this outcome. We did not have sufficient power to determine an interaction between a particular method of cuff closure and subsequent mesh exposure in either the original PACT trial or in this extension study.

Long-term evaluation of rare adverse events related to polypropylene mesh for pelvic organ prolapse repair is important for patient safety [22]. We report that no patients within our cohort experienced a serious late-term mesh complication such as erosion into the bladder or bowel, fistula, severe pain, or bowel obstruction. Our minimally invasive approach, in which either laparoscopic or robotic assistance was employed with no conversions to an open approach, likely contributes to a lower rate of bowel adhesions and subsequent obstruction than open SCP [23].

The third important finding of this longitudinal study is sustained procedural efficacy with 88% of our cohort reporting the absence of a vaginal bulge, no prolapse beyond the hymen, and no retreatment. In our high-risk group of younger women with advanced uterovaginal prolapse, only 1 patient required retreatment with a pessary for stage IV prolapse and there were zero reoperations. Interestingly, women in the delayed absorbable suture group had significantly better pelvic floor symptoms according to the PFDI questionnaire. There is a significant paucity of long-term data of minimally invasive SCP with the use of modern, lighter weight mesh materials. Culligan et al. performed a longitudinal study with almost 5 years of follow-up in which 76% had concomitant hysterectomy, but these were all supracervical. Although they reported a 0% rate of mesh exposure with the use of an ultralightweight mesh, 4% required reoperation for symptomatic recurrence in the mid-vaginal compartments [24]. We believe that cervical removal enhances the ability to successfully reduce significant anterior vaginal wall prolapse as the anterior vaginal wall is shortened and this likely translates into a lower reoperation rate [11].

Mesh weight may also have a significant impact on recurrence risk. Askew et al. reported a higher rate of failure in the anterior compartment when an ultralightweight mesh (<20 g/m^2) was used compared with a heavier weight mesh [21]. In our study, we used the Upsylon™ (Boston Scientific, Boston, MA, USA) mesh, which is considered a lightweight (25 g/m^2) but not an ultralightweight material. Surgeons may have to evaluate the relative risks of mesh exposure as opposed to recurrence risk when deciding on choice of preferred synthetic graft.

There are some important limitations of our study, most notably of which is a follow-up rate of 106 out of 182 (58%) eligible women. This is quite similar to the attrition experience in the extended-CARE study in which 59% of women had follow-up examinations [5]. It is plausible that incident mesh exposure was considerably higher and was simply missed owing to loss to follow-up. We conducted this study during a challenging era in medicine in which the COVID pandemic hampered efforts to engage patients in elective studies. We attempted to overcome this barrier by offering phone interviews only, but recognize that a query regarding symptoms of mesh exposure may not be a valid substitute for visual inspection of the vagina. In addition, the original PACT study was not powered to detect differences in risk of recurrence or rare complications, and therefore, we cannot assume that the choice of suture material for vaginal graft attachment has no impact on these outcomes.

In conclusion, this longitudinal follow-up study provides reassurance to pelvic floor surgeons who are considering offering minimally invasive total hysterectomy and SCP for primary uterovaginal prolapse. We have provided important data regarding low rates of incident mesh exposure, continued procedural efficacy, and an absence of serious late complications. As we are committed to continued monitoring of safety and efficacy regarding the use of abdominal mesh for prolapse repair, additional longitudinal follow-up of this cohort is planned.

Author contributions C.A. Matthews: PI, data collection, manuscript writing; E.M. Myers, B.R. Henley, K. Kenton, J.M. Wu: data collection, manuscript editing; E.J. Geller: statistical analysis, manuscript writing; E. Weaver: data collection and coordination, manuscript editing.

Declarations

Conflicts of interest This study was a physician-initiated trial that was sponsored by Boston Scientific Corporation who manufactured the lightweight mesh used in the original PACT study.

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