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ORIGINAL ARTICLE

Will hysterectomy at the time of sacrocolpopexy increase the rate of polypropylene mesh erosion?

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Abstract Will total abdominal hysterectomy with concomitant sacrocolpopexy lead to polypropylene (Prolene, Ethicon, Somerset, NJ) mesh erosions? Sixty-seven patients demonstrating a stage 2 or more International Continence Society cystocele, rectocele, and uterine prolapse underwent combined sacrocolpopexy and polypropylene mesh fixation and total abdominal hysterectomy. Surgical failure was noted as prolapse of any of the three pelvic compartments with a stage 2 or more recurrence. Sixty-four patients were available for examination, and none demonstrated mesh erosion or recurrent vault prolapse with a median follow-up of 27 months. Four patients experienced a recurrent stage 2 rectocele without any cystoceles or vault prolapse. Performing abdominal hysterectomy with concomitant sacrocolpopexy with polypropylene extensions does not increase the occurrence of synthetic material erosions in the vaginal vault or the anterior or posterior vaginal walls.

Keywords Hysterectomy · Sacrocolpopexy · Cystocele · Rectocele · Mesh erosion

Introduction

An abundance of biologic and/or synthetic materials is successfully utilized for pelvic floor reconstructive surgery, but polypropylene is commonly used in both the USA and Europe. Surgical confidence in the application of a full anterior, middle, and posterior vaginal wall polypropylene mesh extension after hysterectomy may decline, however, with concerns of potential mesh erosion over a new vaginal vault cuff closure. Extensive reports of abdominal hysterectomy with concomitant sacrocolpopexy have reported mesh erosions and infection rates more than 10% [1], perhaps related to this being a clean-contaminated procedure. Our 5-year experience with abdominal hysterectomy and sacrocolpopexy is reported, as well as our anatomic success rates and evaluation of polypropylene mesh erosions.

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Materials and methods

Between January 2002 and September 2005, 67 patients underwent combined total abdominal hysterectomy with and without bilateral salpingo-oophorectomy with simultaneous sacrocolpopexy with two complete polypropylene meshes (6-cm bladder mobilization from the vault apex) for the treatment of International Continence Society (ICS) stage 2 or more pelvic organ prolapse (POP score) of the anterior, middle, and posterior pelvic compartments. Internal Review Board approval was obtained by the participating hospitals. All patients underwent a complete history and physical examination, ICS POP score, Pelvic Floor Distress Inventory (PFDI) scoring, and either multi-channel urodynamics or videourodynamics with their prolapse reduced.

Statistical analysis measurements included medians and ranges with standard deviations of age, follow-up in months, blood loss (ml), operating room time (min), intraoperative cystotomy, mesh erosion, body mass index, number of prior prolapse procedures, hormone replacement therapy, decrease or absence of splinting/digitations, sexually active patients, maintained or improved orgasm, anorgasmic patients, de novo SUI, de novo urgency, and failure rate. As part of a personal satisfaction assessment, patients were asked if they would recommend the operation to a friend (Yes or No), and

if not, why they would not. All patients were followed at intervals of 6 weeks, 6 months, and 12 months, with reassessment between September and October 2006. During this interval, a full-lit vaginal examination with digital rectal examination was performed. In obese patients or those otherwise difficult to examine, a vaginoscopy was performed to assess for vaginal mesh erosion. Also assessed were the patients' POP and PFDI scores, satisfaction with the operation, and presence of erosion (via vaginal and digital rectal examination). Failure criteria included a mesh erosion and an ICS stage 2 or more prolapse. All prolapse assessments were performed by an unaffiliated gynecology nurse with 22 years of ample clinical experience with POP assessment and scoring. Statistical analyses were performed using the Statistical Package for Social Sciences, version 11.0, SPSS, Chicago, IL. Analyses included simple medians and standard deviations where applicable. The association between changes in scores for the UDI-6. 2Q-7, PFDI-20 was measured with Pearson's correlation coefficient. Comparisons in the changes in these three standardized and validated questionnaire scores between preoperative and postoperative results were performed with an analysis of covariance (ANCOVA).

Procedure

With one urogynecologist performing all sacrocolpopexies and eight different gynecologists performing the abdominal hysterectomies, all practitioners agreed to close the anterior vaginal wall with running locking 2-0 Polyglactin 910 (Ethicon, Somerset, NJ, USA), then, separately, the posterior vaginal wall. The vault was closed by re-approximating both the closed anterior and posterior vaginal walls with running locking 2-0 Polyglactin 910 (without a suture free zone). Prior experience has proved that a vault closed with interrupted Polyglactin 910 is susceptible to breaking after an EEA sizer is placed vaginally to outline both the anterior vaginal wall (cystocele repair) and posterior vaginal wall (rectocele and/or enterocele). A size 18 EEA sizer was used to outline the vault, bladder, and rectum for clear delineation of the pelvic compartment parameters. The posterior vaginal wall was outlined with the EEA and the most distal aspect of the posterior vaginal wall was palpated. A 1-0 Polydioxanone (Ethicon) was placed on the right and left sides to reduce the rectocele component as close to the perineal body as possible. A large suture 1-0 Polydioxanone was utilized because experience with so many patients having had voluminous vaginal scarring from multiple vaginal and abdominal procedures for prolapse allowed easier access to the appropriate tissue planes for cystocele and rectocele reduction. An additional group of sutures was placed along the posterior vaginal wall with full thickness bites at 3–4 cm, so a total of six sutures was placed, three on the right and left posterior vaginal wall up to and within 2 cm of the fresh cuff. A 2× 12-in. piece of polypropylene was secured to the posterior vaginal wall with these sutures. Next was a 4–6-cm mobilization of the bladder from the apex of the cuff toward the bladder neck. After mobilization from the anterior vaginal wall, the bladder was carefully filled with 200 ml normal saline to discern if any egress of saline occurred from the posterior bladder wall or the bladder paravaginal sides. If a cystotomy was evident, it was closed in a double-layer fashion, with the first layer a running locking 3-0 Polyglactin 910, followed by a superficial lambertized layer with interrupted 2-0 Polyglactin 910. After closure, the bladder was filled again, this time with indigo carmine to clearly confirm cystotomy closure. Every 2 cm, a row of 2, 1-0 Polydioxanone sutures was placed, one on the right and left sides of the anterior vaginal wall up to and within 1 cm of the cuff. Another piece of 2×12-in. polypropylene mesh was secured with these sutures to the anterior vaginal wall. Both polypropylene meshes were left independent of each other without suture attachment. The sacral promontory was manually palpated with the surgeon's dominant hand. Next, the sacral parietal peritoneum was incised some 4–6 cm distal to the upper border of the sacral promontory. Incision of the peritoneum followed distally, almost to the vertex of the posterior polypropylene mesh. The right and left flaps were undermined, taking care to identify the sacral vascular plexus and minimize contact with it. Both meshes were loosely applied over the concave surface of the sacral foramina, and the prolapse reduction was examined vaginally. With the prolapse well fixated and reduced, four, 5-mm spiral Titanium tacks (ProTack, Tyco Health, Norwalk, CT, USA) tacks were placed through both meshes at the S2 level into the sacral anterior longitudinal ligament and accompanying ossium in lieu of permanent suture. The sacral peritoneum was closed over both meshes with interrupted 3-0 Polyglactin 910, utilizing coverage from the adjacent serosa of the sigmoid colon, rectum, and bladder if necessary. No drains were placed and the peritoneum was not closed. A Foley was placed and removed once the patient became ambulatory.

Results

Sixty-four of 67 patients (14 in 2002, 23 in 2003, 16 in 2004, and 11 in 2005) completed all assessments and were eligible for study inclusion (Table 1). With a median of

Table 1 Patient demographic/data points

Patient characteristics	Data	Range
Median age (years)	55±10	32–73
Medium follow-up (months)	27±9	12–48
Median blood loss (ml)	200±50	100–500
Median operative time (min)	178±33	128–284
Intraoperative cystotomy (%)	5	
Mesh erosion (%)	0	
Median body mass index	32.1±9.5	22.2–43.6
Median prior prolapse procedures	1	0–6
Hormone replacement therapy (%)	56	
Decrease or absent splinting/digitation (%)	74	
Maintained or improved orgasm (%)	90	
Anorgasm patients (%)	10	
De novo SUI (%)	11	
De novo urgency (%)	18	
Failure rate (percent)	8	
Median preoperative PFDI	56±11	30–74
Median postoperative PFDI*	8±4	6–25
Median preOp UDI-6	11±6	5–27
Median PostOp UDI-6*	10±2	5–14
Median preOp 2Q-7	14±5	5–20
Median postOp 2Q-7*	12±2	0–15
Patient satisfaction with operation (%)	93	

*Changes between pre- and postoperative pelvic floor distress inventory (PFDI, n=64), Urinary Distress Inventory scores were statistically significant at p=<0.0001. UDI and 2Q7 on patients were not statistically significant (p=0.61).

27 months' follow-up, our failure rate was 8% (4 rectoceles stage 2, ICS Bp 0,0,0,-1). There were no vault or cystocele failures. Patients' median PFDI scores improved from 53 to 10 (p=0.001), with five patients demonstrating de novo stress incontinence treated by subsequent tension-free vaginal tape or tension-free vaginal tape obturator approach. De novo urgency was experienced by six patients (12%). Overall patient satisfaction was 93% (60/64). Four dissatisfied patients complained of severe pain from both operations with a return to normal activity of about 8 weeks. There were no episodes of mesh erosion nor were there any complaints of abscess or deep vein thrombosis, unexplained fever, ileus, or bowel obstructions. Two patients with a strong history of pulmonary obstructive or cardiovascular disease received blood transfusions for hemoglobin levels less than 10 mg. There were no readmissions within 30 days of hospital discharge. POP-Q point numerical assessment was not available because all patients were POP score measured by a non-affiliated nurse by fulfilling the ICS stage 1 through 4 definitions.

Discussion

Why should practitioners utilize synthetic materials during prolapse surgery and which patients should receive them? Many surgeons believe that with the advent of synthetic materials, substances stronger than a woman's natural tissues can now be interposed to improve outcomes. However, synthetics have not gained widespread acceptance and use in many prolapse procedures other than sacrocolpopexy. While a clearer dichotomy of patients who should have mesh interposition may have been present 10 years ago (primary repair versus secondary repair patients), many surgeons are no longer making a distinction and are offering mesh interposition to primary repair patients, as well. Synthetic materials for urogynecologic and female reconstructive surgical purposes abound; however, their important physiologic attributes should be clearly differentiated to aid in their surgical selection and utilization. The prevention of biosynthetic-related material complications requires in-depth knowledge and understanding of mesh components' physical properties with special emphasis placed on macroporosity, shrinkage, and mesh erosion. The Amid [2] four-point classification was implemented to explain pore size and fiber type (monofilament versus multifilament structure) of synthetic grafts used for abdominal herniorrhaphy repairs. Type 1 grafts are totally macroporous prostheses such as polypropylene, marlex-crystalline polypropylene, and high-density polyethylene (HDPE), with pores >75 μ. Type 2 are microporous <10 μ in at least one of their three dimensions. Type 3 are macroporous with multifilamentous or microporous components such as PTFE (Teflon) braided Dacron (Mersilene) or braided polypropylene mesh (Surgipro), and type 4 are submicronic pore size <10 μ including polypropylene sheeting. Mesh infection may result from the proliferation of bacteria (most with a diameter of 1 micron or less) within biosynthetic materials with a pore size less than 10 μ in each of their three dimensions. Macrophages, granulocytes, and fibroblasts (each greater than 10 μ) will be too large to infiltrate a three-dimensional 10-μ pore. Equally important, a braided suture with these same <10-μ pores will allow bacteria to harbor, prevent accessibility of white blood cells, form scar (wound cytoskeletonization) fibroblasts, obstruct wound healing, and perhaps even facilitate infection by the means elucidated. Type 1 synthetic materials deter the housing of bacteria but secondarily allow rapid fibroplasias and angiogenesis within the wide pores, preventing bacterial infiltration and growth. Type 1 prosthetic infections are caused by the utilization of multifilamentous suture for the fixation of the mesh although they are mistaken for being caused by the mesh itself. With herniorrhaphies, infection rates with type 2 and 3 biosynthetics are a reasonable 9.6–

50%. Such frequency has not been encountered with type 1 materials. Additionally, herniorrhaphies with type 1 meshes do not have to be removed; drainage of the infected area, with local wound and oral antibiotics, are all that is necessary to manage these infections. By contrast, total removal of the type 2 or at least partial removal of type 3 is often necessary. Another important concern is that mesh contraction during the scarring process leads to shrinkage of the mesh after implantation. Radiographic measurements of the distances between the metallic staples used for the preperitoneal mesh repair of incisional hernias made 10 months after implantation reveal a contraction of approximately 20% when compared to measurements taken shortly after the procedure. Biochemical studies have also demonstrated a 20% reduction in pore size during similar periods of healing. Mesh materials, then, can be idealized for each patient, making repairs tension-free to allow for contraction of the materials and a resulting 20% reduction in macroporosity (75 μ reduced to 60 μ for type 1 is not alarming but in type 2 materials, a reduction from 10 to 8 μ will amplify the difficulty of the host immune response to infection). Characteristics of an ideal graft material would include ease of use, economy, absence of erosions or infections, studies demonstrating a greater than 90% success rate in controlling prolapse with a 10-year follow-up, and elicitation of minimal immune and inflammatory bodily responses. The synthetic materials must also withstand the body's attempts at modification by degradation by collagenase, elastase, and other enzymes before establishing tissue neovascularization and collagen ingrowth. Relative contraindications may include (and are subject to the surgeon's experience with biosynthetic materials) pelvic radiation, severe urogenital atrophy, ongoing steroid consumption, immunosuppression, active pelvic or vaginal infections, poorly controlled diabetes, heavy smoking, and/or morbid obesity. Caution has discouraged the use of any mesh for sacrocolpopexy with complete bladder mobilization with concomitant abdominal hysterectomy. An open vaginal vault that is later closed may allow the clean contaminated area to be infiltrated with various vaginal bacilli. However, full bladder mobilization for sacrocolpopexy after hysterectomy with a type 1 macroporous polypropylene mesh may, in fact, afford a good anatomical result with acceptable mesh complications. The cause for mesh erosion has not been clarified, but a few studies suggest that combining abdominal hysterectomy with sacrocolpopexy may increase the risk of mesh erosion through the anterior or posterior vaginal wall. Many supporters of this conclusion believe that the new apical vaginal cuff incision may be the origin of the erosion. Imparato et al. [1] described 71 women who underwent sacrocolpopexy, 57 with concurrent hysterectomy. Twenty-one of the 57 women had a synthetic mesh interposition, while the remaining 36 had the vaginal vault directly fixed with suture to the sacral anterior longitudinal ligament. Mesh erosion occurred in 3/21 (14%) with concomitant hysterectomy (two women had Teflon mesh, E.I. Dupont de Nemours, Wilmington, DE, and one had Mersilene mesh, Johnson & Johnson, Somerville, NJ). Additionally, Culligan et al. [3] reported mesh erosion occurrences in 3/11 women (27%) who underwent sacrocolpopexy and abdominal hysterectomy, compared with 3/224 (1.3%) who did not ($p<0.001$). In their study, the type of mesh utilized was not indicated. In another similar comparative study, Thompson et al. (unpublished data) reported mesh erosion in 3/22 women (13.6%) undergoing both procedures simultaneously, compared with 1/121 (0.7%) who underwent sacrocolpopexy alone ($p<0.05$). Conflicting studies exist, however, as Brizzolara and Pillai-Allen [4] reported on a group of 60 patients undergoing simultaneous procedures without mesh erosion while patients in the nonhysterectomy sacrocolpopexy group had an erosion rate of 1.5% (1/64). Brizzolara and Pillai-Allen had utilized polypropylene or an allograft for the interposition with Gore-Tex suture. Our study describes a set of 64 patients who underwent sacrocolpopexy and hysterectomy with polypropylene 2×12-in. mesh strips and 1-0 polydioxanone, both from Ethicon. All patients had the same style of vault closure and the same mesh material. In this series of concomitant cases with dual full mesh interpositions, the surgeon utilized polypropylene exclusively, and no mesh or suture erosions were noted on multiple periodic examinations. Although this study revealed good short-term outcomes and no erosions, it is still important to understand that long-term term outcomes (>10 years) may reveal a more significant mesh erosion rate.

While there are no ideal synthetic graft materials, polypropylene was chosen because it is a type 1 mesh that has demonstrated ease of use and a decrease in infection rates while also maintaining an excellent safety profile. This surgeon has used polypropylene exclusively for sacrocolpopexy since 2001. The downside to polypropylene for sacrocolpopexies is few randomized studies comparing its efficacy to other more studied mesh synthetics including mersilene. Minimal resilience to deformation makes polypropylene somewhat more difficult to work with, but only marginally so compared to most meshes. However, with the aforementioned encouraging results, the use of polypropylene mesh for concomitant sacrocolpopexy and abdominal hysterectomy may be approached with less trepidation. This study demonstrates a good short-term efficacy of concomitant hysterectomy with sacrocolpopexy with polypropylene mesh because of the polypropylene's inherent mesh properties that decrease potential complications like mesh infection or erosion.

Both critics and proponents of the utilization of mesh interposition for sacrocolpopexy will, over time, complete randomized, thorough studies describing mesh utilizations

for abdominal and vaginal prolapse surgeries. At this time, we rely on current nonrandomized patient cohort studies and personal experience to guide our opinion and surgical intervention. Our experience gives credence to both these operations safely coexisting and ameliorating prolapse symptoms with minimal surgical morbidity.

Conclusions

Performing abdominal hysterectomy and concomitant sacrocolpopexy with 2-in. polypropylene mesh extension does not, in the short-term (27-month follow-up), lead to an unacceptable rate of mesh erosion (0%). Interoperative complication rates (cystotomy) were not unacceptable at 5% with no major complications such as abscesses, bowel obstructions, or unexplained fevers.

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