UROGYNECOLOGY

Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study

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OBJECTIVE: The purpose of this study was to describe the evaluation and management of synthetic mesh-related complications after surgery for stress urinary incontinence (SUI) and/or pelvic organ prolapse (POP).

STUDY DESIGN: We conducted a multicenter, retrospective analysis of women who attended 4 US tertiary referral centers for evaluation of mesh-related complications after surgery for SUI and/or POP from January 2006 to December 2010. Demographic, clinical, and surgical data were abstracted from the medical record, and complications were classified according to the Expanded Accordion Severity Classification.

RESULTS: Three hundred forty-seven patients sought management of synthetic mesh-related complications over the study period. Index surgeries were performed for the following indications: SUI (sling only), 49.9%; POP (transvaginal mesh [TVM] or sacrocolpopexy only), 25.6%; and SUI + POP (sling + TVM or sacrocolpopexy), 24.2%. Median time to evaluation was 5.8 months (range, 0–65.2). Thirty percent of the patients had dyspareunia; 42.7% of the patients had mesh erosion; and 34.6% of the patients had pelvic pain. Seventy-seven percent of the patients had a grade 3 or 4 (severe) complication. Patients with TVM or sacrocolpopexy were more likely to have mesh erosion and vaginal symptoms compared with sling only. The median number of treatments for mesh complications was 2 (range, 1–9); 60% of the women required ≥2 interventions. Initial treatment intervention was surgical for 49% of subjects. Of those treatments that initially were managed nonsurgically, 59.3% went on to surgical intervention.

CONCLUSION: Most of the women who seek management of synthetic mesh complication after POP or SUI surgery have severe complications that require surgical intervention; a significant proportion require >1 surgical procedure. The pattern of complaints differs by index procedure.

Key words: mesh excision, mesh-related complication, sling, synthetic mesh

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Approximately 11% of women in the United States will require surgical intervention for either pelvic organ prolapse (POP) or stress urinary incontinence (SUI) by age 80 years. Of these women, up to 29% will undergo repeat surgery for symptom recurrence.[1,2] In response to these high recurrence rates, the placement of synthetic mesh during repair is being used increasingly in hopes of achieving more durable improvement.[3] Current evidence suggests that, although the use of such mesh may reduce objective symptom recurrence when compared with native tissue repair only, complications appear to increase.[4-6] Common complications include intraoperative bladder perforation, mesh erosion, chronic pelvic pain, dyspareunia, infection, and fistula formation.[4-16]

How to best balance the potential benefit of improved outcomes with the well-demonstrated risk of repair-related complications remains unclear. The Food and Drug Administration has responded by first issuing a public health warning in October 2008, which was followed by a safety communication in July 2011.[17,18] These warnings highlight the need for a thorough informed consent process but leave the ultimate decision regarding the use of synthetic mesh between clinician and patient. The purpose of this study was to describe the evaluation and management of complications from synthetic mesh after surgery for SUI and POP that were evaluated at 4 US tertiary referral centers. Results were intended to help elucidate the nature of possible complications, the context/circumstances in which they are most likely to occur, and the additional treatment that is typically required for managing these complications.

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TABLE 1
Current Procedural Terminology and *International Classification of Diseases*, 9th Revision, codes used to identify potential subjects

Type of code	Code and explanation
Current Procedural Terminology	57267 Insertion of mesh or other prosthesis for repair of pelvic floor defect
	57295 Revision or removal of prosthetic vaginal graft (vaginal approach)
	57296 Revision or removal of prosthetic vaginal graft (abdominal approach)
	57426 Revision or removal of prosthetic vaginal graft (laparoscopic approach)
	57287 Revision or removal of sling for stress incontinence
International Classification of Diseases, 9th Revision	619.0 Fistula involving female genital tract
	623.2 Vaginal stricture
	625.0 Dyspareunia
	625.5 Pelvic pain syndrome
	625.9 Pelvic pain unspecified
	719.45 Pain, joint, pelvic region
	729.6 Foreign body in soft tissue
	788.20 Retention of urine
	788.21 Incomplete bladder emptying
	936 Foreign body in intestine or colon
	938 Foreign body in alimentary tract
	939.0 Foreign body in bladder or urethra
	939.2 Foreign body vulva or vagina
	939.9 Foreign body in genitourinary tract
	959.9 Foreign body
	996.30 Mechanical complication of genitourinary device implant and graft
	996.65 Infection and inflammatory reaction because of genitourinary device, implant, or graft
	996.76 Mesh erosion
	V58.32 Removal of suture

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(continued)

TABLE 1
Current Procedural Terminology and *International Classification of Diseases*, 9th Revision, codes used to identify potential subjects *(continued)*

Materials and Methods

This was a multicenter, retrospective analysis of all women who attended 4 US tertiary referral centers for evaluation and/or management of a complication that resulted from synthetic mesh placed during surgery for SUI and/or POP. The 4 sites included Cleveland Clinic (Cleveland, OH), The Christ Hospital (Cincinnati, OH), MedStar Washington Hospital Center (Washington, DC), and Women & Infants Hospital of Rhode Island (Providence, RI). All sites obtained individual institutional review board approval.

All sites underwent training to follow standardized data abstraction procedures. To identify potential subjects, a search of the medical/billing records was performed with the use of a uniform set of Current Procedural Terminology and International Classification of Diseases, 9th Revision, codes (Table 1). To reduce irrelevant results, sites were allowed to limit their search to patients of only those practitioners (including both gynecologists and urologists) who were known to have managed vaginal mesh complications. The charts of all potential subjects were screened by site-specific study personnel to determine whether eligibility criteria were met. To qualify for inclusion in the study, the patient had to undergo the index surgery in which synthetic mesh was initially placed on or after Jan. 1, 2006. Selection of this date was intentional because it represents the introduction of vaginal mesh use for treatment of POP and thus allows for a fairer comparison of the proportion of complications that result from the mesh that was used for SUI vs POP. Qualifying index surgeries included the following procedures during which synthetic mesh was placed (cases of biologic mesh use were not considered): (1) midurethral slings, (2) transvaginal mesh, kit or non-kit (TVM), (3) sacrocolpopexies, and (4) any combinations of 1-3. It was not required for the index surgery to have been performed at the study site. Subjects were included if they came to the study site for evaluation and/or management of a mesh-related complication by December 31, 2012, regardless of the type of treatment (eg, inpatient vs outpatient, conservative vs invasive), if any, that had been received at each respective study site.

For all eligible subjects, the following information was collected: demographics, medical history, information about the index surgery, nature of the synthetic mesh complication, management of the synthetic mesh complication, and classification of the mesh complication. Demographic and medical history data included age, race, parity, height, weight, hormonal status, smoking status, and relevant comorbidities (chronic steroid use, diabetes mellitus, and connective tissue disorders). Index surgery data included the date of the index surgery, location (whether it occurred at the study site), indication (SUI, POP, or both), exact procedure, approach, type/brand of synthetic mesh