Outcome of Transvaginal Mesh and Tape Removed for Pain Only

Jack C. Hou, Feras Alhalabi, Gary E. Lemack and Philippe E. Zimmern*

Department of Urology, University of Texas Southwestern Medical Center at Dallas, Dallas, Texas

Abbreviations and Acronyms
${\sf MTR}={\sf mesh}$ or tape removal
MUS = mid urethral sling
VAS = visual analog scale

Accepted for publication April 7, 2014. * Correspondence: Department of Urology, University of Texas Southwestern Medical Center at Dallas, 5323 Harry Hines Blvd., J8 122, Dallas, Texas 75390-9110 (e-mail: <u>Philippe.Zimmern@</u> <u>UTSouthwestern.edu</u>). **Purpose**: Because there is reluctance to operate for pain, we evaluated midterm outcomes of vaginal mesh and synthetic suburethral tape removed for pain as the only indication.

Materials and Methods: After receiving institutional review board approval we reviewed a prospective database of women without a neurogenic condition who underwent surgery for vaginal mesh or suburethral tape removal with a focus on pain as the single reason for removal and a minimum 6-month followup. The primary outcome was pain level assessed by a visual analog scale (range 0 to 10) at baseline and at each subsequent visit with the score at the last visit used for analysis. Parameters evaluated included demographics, mean time to presentation and type of mesh or tape inserted.

Results: From 2005 to 2013, 123 patients underwent surgical removal of mesh (69) and suburethral tape (54) with pain as the only indication. Mean followup was 35 months (range 6 to 59) in the tape group and 22 months (range 6 to 47) in the mesh group. The visual analog scale score decreased from a mean preoperative level of 7.9 to 0.9 postoperatively (p = 0.0014) in the mesh group and from 5.3 to 1.5 (p = 0.00074) in the tape group. Pain-free status, considered a score of 0, was achieved in 81% of tape and 67% of mesh cases, respectively. No statistically significant difference was found between the groups.

Conclusions: When pain is the only indication for suburethral tape or vaginal mesh removal, a significant decrease in the pain score can be durably expected after removal in most patients at midterm followup.

Key Words: urethra, pelvic pain, suburethral slings, surgical mesh, device removal

SINCE the mid 1990s, synthetic mesh slings have become the dominant treatment of stress urinary incontinence, replacing traditional, well established techniques such as autologous fascial slings and Burch colposuspension.¹ In addition, synthetic mesh materials have become popular for various transvaginal pelvic floor prolapse reconstructive surgeries in the last decade. Complication types, rates and management strategies were reported for these synthetic meshes and slings.² Despite rapid accrual in the contemporary literature on this specialized management several unanswered questions remain on optimal management.³

However, a domain for which little is known to date is pelvic pain after vaginal tape/mesh surgery, especially when considered in isolation and not with an associated complication such as vaginal exposure. The option of mesh or sling removal surgery for pelvic pain relief was suggested. To date the literature includes mostly case reports or small series with a limited number of patients, short followup and no objective tool by which to measure pain at baseline and its degree of improvement after removal surgery.⁴⁻⁷

Therefore, we specifically studied the pain symptom outcome in women who underwent MTR surgery for persistent pelvic pain as the only indication for operation.

MATERIAL AND METHODS

After receiving institutional review board approval we analyzed a prospectively collected database from 2005 to 2013 of women without a neurogenic condition who underwent surgery to remove vaginal mesh or tape only because of persistent pain after original placement and had a minimum 6-month followup. Study exclusion criteria included MTR surgery for pain associated with any of certain complications, including mesh exposure, mesh erosion, recurrent urinary tract infections and urinary retention/obstruction. The single reason for tape or mesh removal surgery was pain.

The primary outcome was the pelvic pain level assessed by a simple VAS (range 0 to 10) recorded at baseline at arrival to the clinic by a nurse blinded to patient condition and similarly recorded at each subsequent visit. We evaluated demographics, mean time to presentation after initial placement surgery, pain site and type of mesh or tape. Baseline pain scores were compared with VAS scores at the last visit recorded in the electronic medical record. Pain-free status was defined as a VAS pain score of zero.

The surgical technique of tape removal was reported previously.^{8,9} During MUS removal urethrocystoscopy is first performed with a 17.5Fr female urethroscope to locate the course of the tape, which often provokes urethral floor flattening or elevation. A short transverse vaginal incision is then made over the course of the tape to permit access to the lateral extensions of the tape, better control bleeding and facilitate the repair of urethral injury if one occurred during MUS excision. The vaginal incision can be extended into an inverted U shape to allow for insertion of a Martius fat pad graft and/or a fascial patch as covering layers over urethral repair. To minimize the risk of urethral injury the tape is located on the side of the urethra at the 3 or 9 o'clock position and divided there.

The medial end of the divided tape is grasped with a short Allis clamp, lifted and peeled off the undersurface of the urethra from one side to the other. The lateral extensions of the mesh past the inferior edge of the pubic ramus toward the obturator fossa for total obturator tape or the upper arms of the tape extending toward the retropubic space for transvaginal tape are usually left intact to maintain some urethral support.

Urethrocystoscopy is repeated after suburethral tape removal to ensure that no urethral injury occurred and the urethral lumen returned to normal. Each removed segment is sent for pathology review for medicolegal documentation after being photographed.

For mesh removal the same method is used. As much mesh as possible is removed transvaginally whether it be anterior, posterior, apical, at some or at all of these locations, including the arms of these meshes extending as lateral as possible.

We analyzed the change in pain score between preoperative and postoperative visits, and used the last visit VAS score recorded in the electronic medical record. The Student t-test was used for statistical analysis with p < 0.05 considered significant.

RESULTS

From a database of 271 patients who underwent MTR during the study period we excluded 148, leaving 123 available for final analysis. Of the 148 excluded patients 92 had urinary obstruction/retention symptomatology, 87 had recurrent urinary tract infections, 42 had mesh extrusion, 4 underwent tape plus mesh removal at the same time and 11 had mesh erosion. Many women met more than 1 exclusion criterion. Of the 123 patients included on final analysis 69 and 54 underwent transvaginal mesh and suburethral tape removal, respectively. No patient had undergone a prior tape or mesh removal attempt.

Of the women 90% were white, 7% were Hispanic and 3% were black. Mean age at presentation was 52.8 years (range 38 to 72) and mean body mass index was 28 kg/m² (range 23 to 38). Mean time to presentation to our office since MTR surgery was 31 months (range 8 to 72). In the transvaginal mesh removal group the mesh was Avaulta® in 16% of cases, Prolift® in 39%, PerigeeTM or ApogeeTM in 9%, Elevate® in 21% and unspecified in the operative report in 15% (see table). The mean pain score preoperatively was 7.9 (range 5 to 10), which decreased to 0.9 (range 0 to 3) at a mean postoperative followup of 22 months (range 6 to 47) (p = 0.0014). In the suburethral tape removal group the

Demographics and pain outcome in women who underwent transvaginal mesh and suburethral tape removal for pain

0			
	Mesh	Tape	p Value
No. pts	69	54	
Mean age (range)	49 (41-63)	53 (38-72)	0.09
Mean kg/m ² body mass index (range)	30 (23-38)	27 (24-36)	0.8
Mean placement-presentation interval (mos)	33 (10—68)	29 (8—72)	0.71
No. mesh type (%):		_	_
Prolift	27 (39))	
Elevate	14 (21))	
Avaulta	12 (16))	
Perigee/Apogee	6 (9))	
Unknown	10 (15))	
No. tape type (%):			_
Retropubic sling		26 (48)	
Transobturator sling		21 (39)	
Mini-sling		3 (5)	
Unknown		4 (8)	
Mean pain VAS score (range 0-10):			
Preop	7.9	5.3	0.068
Last postop visit	0.9	1.5	0.07
No. pain free (VAS 0)	46	44	_
No. persistent pain (no VAS change)	11	3	_

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