Long-term Follow-up of the Virtue Quadratic Male Sling

Andrew N. McCall, Marcelino E. Rivera, and Daniel S. Elliott

OBJECTIVE To report our long-term outcomes of Virtue Quadratic (VQ) sling since male slings have been introduced as a potential alternative treatment option to the artificial urinary sphincter (AUS), with limited long-term data available for proof of efficacy. Herein, we report our data.

METHODS A retrospective review was performed on all Virtue slings performed at our institution over a 2-year period. Patient-reported outcomes regarding procedure success, complications, as well as subsequent procedures were identified. Procedure failure was defined as the inability to reduce patient's preoperative pad use, sling explant for complications, and need for AUS due to continued incontinence.

RESULTS We identified 32 consecutive male patients who were implanted with the VQ sling over the study period. One patient was excluded due to no follow-up. Median follow-up was 55 months. Median preoperative and postoperative pads per day were 3 (interquartile range: 1-3) and 2 (1-2.5). There were 21 (68%) patients who were considered procedure failures. Two (7%) patients reported chronic pain following placement and 7 (22%) underwent subsequent sling explant due to pain or for failure (1 vs 6). Six (20%) patients underwent subsequent AUS placement. Failure was more likely in patients with external beam radiation therapy (6, 19%) (P = .02). There was no association between procedure failure with age (P = .65) or severity of incontinence (P = .17).

CONCLUSION This study demonstrated a significant procedure failure and complication rate with the VQ sling. Thus, we do not recommend the use of the VQ sling and have abandoned all further implantation of the device. UROLOGY 93: 213–216, 2016. © 2016 Elsevier Inc.

The concept of urethral compression to manage incontinence was first reported in the 18th century by Heister, with a device that closely resembles a Cunningham clamp.[1] The inception of Berry's implantable prosthetic device in 1961 marked a new era of management for males with urinary incontinence; however, due to significant side effects, his device did not gain widespread acceptance. Kaufman described multiple techniques utilizing compression of the urethra, but it was not until the 1970s that these ideas became reality through male urethral slings and the implantable artificial urinary sphincter (AUS).[1]

With greater than 100,000 prostatectomies performed per year with a 9%-20% risk of incontinence, treatment of postprocedural urinary incontinence following prostatectomy is a common clinical issue treated by urologists.[2-4] Of patients who undergo prostatectomy, 5% are expected to be treated with surgery for urinary incontinence over a 15-year period.[5] For the last 30 years, the AUS has remained the gold standard for male stress urinary incontinence. More recently, several models of the male urethral sling have been developed as an attempt at a more "minimally invasive" approach to treatment. Four techniques have been described: bone-anchored sling, readjustable sling, transobturator sling systems, and transobturator with a prepubital component. Welk and Herschorn examined outcomes and adverse events of bone-anchored sling, transobturator sling systems, readjustable sling in 2010, with actual cure rates ranging from 16% to 75%, from 9% to 4%, and from 40% to 66%, respectively; however, to our knowledge, there is no long-term follow-up for transobturator with a prepubital component slings in existence, in particular the Virtue Quadratic (VQ) sling (Coloplast, Humlebaek, Denmark).[5] Therefore, we aim to evaluate long-term outcomes in those patients who underwent male urethral sling placement with the VQ sling at our institution.

METHODS

After obtaining Institutional Review Board approval, we identified 32 male patients who were implanted with the

Financial Disclosure: *The authors declare that they have no relevant financial interests.*

From the Department of Urology, Section of Pelvic and Reconstructive Surgery, Mayo Clinic, Rochester, MN

Address correspondence to: Daniel S. Elliott, M.D., Department of Urology, Section of Pelvic and Reconstructive Surgery, Mayo Clinic, 200 First Street SW, Rochester, MN 55905. E-mail: Elliott.Daniel@mayo.edu

Submitted: February 11, 2016, accepted (with revisions): March 8, 2016

VQ sling at Mayo Clinic (Rochester, MN) over a 2-year period ending in January 2012. A retrospective review was performed to identify preoperative patient clinical characteristics and postoperative outcomes (urinary retention, postoperative pain, postoperative incontinence, and secondary incontinence procedures). Inclusion and exclusion criteria (male, adult, and only quadratic sling) statistical analysis was preformed to identify sling success and associated factors contributing to surgical outcomes.

With regard to technique, all VQ slings (Coloplast) were implanted by a single surgeon, with the surgical technique previously described with either a 3, 4, or 5-arm fixation with plication.[6] Figure 1 shows the technique with a 4-arm fixation, with the two lower arms fixed to the obturator membrane, respectively, and the two upper arms angled to be fixed 2 cm superior to the pubic symphysis on the anterior abdominal wall approximately 8 cm apart.

Individual charts were reviewed to evaluate pertinent clinical and surgical comorbidities, in particular prior radiation therapy, age, prostate procedure, comorbidities, and severity of postprocedural incontinence (PPI) (assessed through number of pads per day [PPD]). The retrospective nature of this study precluded a standardized follow-up protocol in all patients. However, all participating patients are followed via office evaluation on an as-needed basis, as determined by their continence or other concerns. Details regarding sling outcomes were obtained from last office examination, any available subsequent operative report, written and/or telephone correspondence, and included current level of incontinence (PPD), postoperative pain, and any additional procedures. Procedure failure was defined as no change in postoperative pad use, failure to reduce leakage <2 PPD, need for placement of an artificial genitourinary sphincter, and/or sling explant secondary to complications.

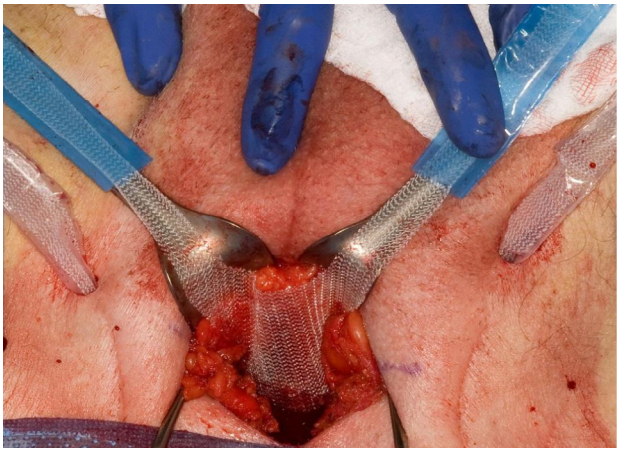

Figure 1. Quadratic sling implantation. (Color version available online.)

Fisher's exact test was used for categorical variables (due to low expected counts), two-sample *t* tests (assuming unequal variance) were used to compare continuous variables, and Mann-Whitney *U* tests were used to analyze median values. All statistical tests were two sided and *P* values less than .05 were considered to be statistically significant. All analyses were conducted using JMP, Version *10* (SAS Institute Inc., Cary, NC, 1989-2012).

RESULTS

From October of 2009 to January of 2012, 32 patients underwent VQ sling placement at Mayo Clinic Rochester. The median patient age in years was 72 (64.5-77). Median patient body mass index was 29 (28-31). One patient was excluded due to loss to follow-up. The median patient follow-up in months was 55 (30-69). Patient demographics are described in Table 1. Patient incontinence was due to stress urinary incontinence and/or intrinstic sphincter deficiency following surgical or radiotherapy. Twenty-nine patients underwent retropubic or robotic radical prostatectomy, 1 patient underwent radiation therapy with brachytherapy, and 1 patient underwent photovaporization of the prostate. Of these patients, 6 (19%) had completed adjuvant external beam radiation therapy following prostatectomy prior to sling procedure. Previous incontinence procedures were performed in 4 (13%) patients with either collagen or Coaptite urethral injections. The median preoperative PPD was 3 (1-3), with 3 men requiring just 1 PPD. The median postoperative PPD was 2 (1-2.5). In our cohort, postoperative urinary retention occurred in 14 (44%) patients, with an interquartile range of 0-2.5 days. Due to pain or procedure failure, 7 (22%) patients underwent subsequent sling removal (1 vs 6). Of these, 6 (18%) patients underwent subsequent AUS placement. Overall, 2 (7%) patients complained of significant chronic pain following placement. No slings were explanted due to device infection. One patient refused AUS

Table 1. Patient demographics with success and failure

Characteristic	Success (n = 10)	Failure (n = 21)	*P* Value
Median age (years) (IQR)	70.5 (63-77)	73 (66-77)	.75
Median BMI (IQR)	30 (28-32)	28 (27-30)	.35
Preoperative radiation (%)	0	29	**.02**
Diabetes (%)	6	5	.37
Hypertension (%)	70	48	.28
Hyperlipidemia (%)	70	62	.59
Cardiac disease (%)	10	29	.11

BMI, body mass index; IQR, interquartile range.
Value in bold indicates $P < .5$, considered statistically significant.