The Bone Anchor Suburethral Synthetic Sling for latrogenic Male Incontinence: Critical Evaluation at a Mean 3-Year Followup

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Abbreviations and Acronyms

ALPP = abdominal leak point pressure

AUS = artificial urinary sphincter

BAUS = bone anchored suburethral synthetic sling

FUL = functional urethral length

MUCP = maximal urethral closure pressure

QOL = quality of life

RRP = radical retropubic prostatectomy

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Purpose: We retrospectively report objective and subjective outcomes in 40 male patients who underwent bone anchored suburethral synthetic sling positioning for stress urinary incontinence due to intrinsic sphincter deficiency.

Materials and Methods: Patients with stress urinary incontinence due to radical retropubic prostatectomy (32), robot assisted laparoscopic prostatectomy (3) and transurethral prostate resection (5) underwent bone anchored suburethral synthetic sling positioning between December 2002 and December 2007. Mean followup was 35.2 months (range 2 to 62). Previous anti-incontinence procedures, radiotherapy and transurethral procedures due to urethral stricture were performed in 5, 11 and 5 patients, respectively. Before and after surgery patients were evaluated by physical examination, urethral cystoscopy, urodynamics, a 1-hour pad test and a quality of life questionnaire. Patients were stratified into 3 groups, including group 1—cured (dry with a pad weight of 0 to 1 gm), group 2—improved (mild to moderate incontinence with a pad weight of 2 to 50 gm) and group 3—failed (patient condition unchanged with a pad weight of greater than 50 gm). **Results:** At the final followup visit 22 (55%), 5 (12.5%) and 13 patients (32.5%) were cured, improved and failed, respectively. Mean pad weight significantly decreased to 51.3 gm in 54% of cases, while the mean total questionnaire score significantly increased to 72.9 in 65% and abdominal leak point pressure significantly increased to 92.5 cm H₂O in 52%. Statistical analysis showed a significant association between preoperative radiotherapy and treatment failure (85% of patients). Complications were perineal pain in 73% of cases, detrusor overactivity in 5% and sling infection in 15%.

Conclusions: The bone anchored suburethral synthetic sling is a simple and attractive procedure that can produce immediate good results with low morbidity, especially when strictly selected patients are treated. Radiotherapy remains a strong predictor of failure.

Key Words: urethra, urinary incontinence, male, prostatectomy, surgical mesh

SPHINCTERIC male incontinence affects 2.5% to 67% of patients following radical, simple, open or transurethral prostatectomy. 1,2 Conservative management for this disease with pelvic floor muscle training, biofeedback, electrical stimulation and extracorpo-

real magnetic innervation, and pharmacological treatment are usually suggested with variable outcomes.^{3,4} Nevertheless, when these approaches fail or urinary incontinence is moderate to severe, invasive options are often needed. Although AUS implanta-

tion provides better results at long-term followup, the complexity of the mechanical device, the need for manual dexterity to manipulate the scrotal pump and the reported revision rate of more than 20% after 5 years have spurred an interest in alternative surgical procedures, such as transurethral injection of bulking agents, periurethral balloons or suburethral sling positioning. ^{5–8} In particular passive urethral compression by suburethral slings has shown good results, especially using synthetic slings, which can provide higher and more lasting tensile strength than biological or mixed slings. ⁹

We report our experience with BAUS implantation. We critically evaluated its efficacy and morbidity.

MATERIALS AND METHODS

Patients

In March 2008 we retrospectively assessed 40 male patients 56 to 78 years old (mean \pm SD age 66 \pm 6.3) who underwent the BAUS procedure for iatrogenic urinary incontinence between December 2002 and December 2007. Mean followup was 35.2 months (range 2 to 62).

Preoperative Evaluation

All patients reported severe urinary incontinence (more than 4 pads per day) due to intrinsic sphincter deficiency at least 1 year after RRP (32 or 80%), robot assisted laparoscopic prostatectomy (3 or 7.5%) or transurethral prostate resection (5 or 12.5%). All patients previously underwent pelvic floor exercises with no improvement in urinary incontinence. Three patients (7.5%) were unsuccessfully treated with transurethral injection of bulking agents, while 2 (5%) underwent explantation of the AMS 800™ artificial urinary sphincter due to urethral erosion. A total of 11 patients (27.5%) received radiotherapy 13 months before the anti-incontinence procedure. Five patients (12.5%) presented with urethral stricture, which was secondary to radiotherapy in 3. They underwent transurethral procedures to resolve the condition 6 months before sling implantation (table 1).

Patient evaluation included medical history, physical examination, routine laboratory tests and flexible urethral cystoscopy to exclude urethral stricture and/or bladder neck contracture. In addition, multichannel urodynamic measurement was made of filling and voiding phases with water medium fill cystometry performed using a transurethral, double lumen, fluid filled 10Fr catheter. Urethral pressure profilometry was done with an 8Fr dual sensor microtransducer catheter (Millar Instruments, Houston, Texas), which was withdrawn at a rate of 1 mm per second. ALPP was recorded with the patient supine and the bladder filled with 200 ml sterile water.

Patients also underwent a 1-hour pad test in accordance with International Continence Society guidelines¹⁰ and completed a QOL questionnaire¹¹ with a nonpartisan health care provider. The physician and questioner were blinded to each other. This specific incontinence QOL questionnaire contains 22 items, each with a 5-point Likert-type scale from 1 to 5, yielding a total score of 22

Table 1. Patient characteristics before BAUS

No. pts	40	
Mean ± SD age	66	± 6.3
No. prostatectomy (%):		
RRP	32	(80)
Transurethral prostate resection	5	(12.5)
Robot assisted laparoscopic prostatectomy	3	(7.5)
No. urinary incontinence (%):*		
Mild	0	
Moderate	0	
Severe	40	(100)
Mean ± SD pad wt (gm)	110.6	6 ± 59.2
Mean ± SD total QOL score	25.7	7 ± 8.5
Mean ± SD urodynamics:		
ALPP (cm H_2O)	39.5	5 ± 33.7
MUCP (cm H_2O)	32.5	5 ± 21.2
FUL (cm)	3.3	3 ± 1.2
No. previous (%):		
Anti-incontinence surgery	5	(12.5)
Radiotherapy	11	(27.5)
Urethral stricture	5	(12.5)

^{*} No patients had urge incontinence.

to 110. The use of this questionnaire in patients with iatrogenic urinary incontinence has been previously reported. 12

Surgical Technique

With the patient in the lithotomy position a vertical midline perineal incision was made, and skin and subcutaneous tissues were dissected. Four bone screws, each attached to a pair of No. 1 polypropylene sutures, were inserted into the inner aspect of the inferior rami of the pubic bone with an InVanceTM bone anchoring system. Using a minimal subcutaneous dissection procedure the bulk of fibrofatty tissue on top of the bulbospongiosus muscle was maintained and silicone coated surgical mesh was placed on the fibrofatty tissue at the level of the bulbar urethra without having to expose and dissect the bulbospongiosus muscle. Sling tension was adjusted by tightening the sutures as much as possible to ensure sufficient occlusion of the bulbar urethra. Patients were discharged home on postoperative morning 1 when post-void residual urine was less than 50 ml.

Postoperative Evaluation

Postoperative followup included an initial visit 30 days after surgery. Further visits were scheduled at 6 and 12 months, and every year for 5 years thereafter. During the visit all patients underwent physical examination with a stress test, urodynamic measurement, post-void residual urine evaluation by ultrasonography and a 1-hour pad test. They also completed the self-assessment QOL questionnaire. In addition, at 6 and 12 months all patients underwent retrograde and voiding cystourethrography, and/or urethral cystoscopy.

Following physical examination and the pad test the patients were stratified into 3 groups, including group 1—cured (perfectly dry on the stress test with a pad weight of 0 to 1 gm), group 2—improved (mild to moderate incontinence with a pad weight of 2 to 50 gm) and group 3—failed (condition unchanged or worse with a pad weight

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