Suburethral slings for postprostatectomy stress urinary incontinence

Kevin V. Carlson, MD, FRCSC

The purpose of the Point / Counterpoint section is to encourage vigorous and informed discussion on controversial issues in urology through the presentation of diverse opinions. We aim for a dispassionate discussion of controversies, recognizing that strong passions may exist in support of some positions.

Once the decision has been made to intervene for postprostatectomy stress urinary incontinence (PPI), how do we choose the best therapy for a given patient? The "gold standard" of treatment for these patients has traditionally been the artificial urinary sphincter (AUS), introduced in 1972. Refinements of the AUS ultimately lead to production of the AMS 800 (American Medical Systems, Inc.) and this remains the device in most widespread use. Experience with the AMS 800 now spans nearly 35 years: the 100 000th device was implanted in 2006 (Buddy Snow, Product Manager, Male Continence, American Medical Systems, Inc.: personal communication, 2008) and extensive data has been published. Indeed, the AMS 800 has become an old friend to urologists worldwide.

Reports from single-institution studies indicate that the AUS is a safe and effective means of improving or curing PPI in appropriately selected men, and satisfaction rates are high. Success rates in these series range from 70% to 90%.[1–7] A recent US nation-wide study, however, reported that most men continue to require pads 2 to 5 years after implantation.[8] With time, there is also significant likelihood that patients will require repeated interventions to manage complications or recurrent incontinence.[1–8] Complications may include infection (0%–3%) and urethral erosion (0%–13%), both necessitating removal of the device.[1–8,9] Recurrent incontinence may be due to urethral atrophy, mechanical failure or device fatigue, and this may necessitate complete device replacement, insertion of a second cuff, or changing to a smaller cuff or higher pressure reservoir. The ideal solution for a given patient is never certain, and the likelihood of long-term subsequent efficacy cannot be guaranteed. Overall, about 15%–30% of patients with implants will require surgical revisions over 5–13 years follow-up.[1–9] Other drawbacks to the AUS include the fact that the user is required to have adequate manual dexterity and cognition to work the pump, and that he must also accept the need for the device to remain unactivated for 6 weeks postoperatively.

The ideal treatment for established PPI would be a minimally invasive, outpatient procedure with superior, immediate and permanent efficacy, no moving parts, no significant voiding obstruction, low cost and minimal morbidity. With these goals in mind, efforts have burgeoned in the development of suburethral slings for the treatment of PPI.

Slings function by providing passive, fixed urethral compression that prevents leakage during bladder storage, which can be overcome during voiding by increasing intra-abdominal pressure. The work of Berry[10] in the 1960s and Kaufman and Raz,[11–13] and Kishev and colleagues[14] in the 1970s was instrumental in confirming the potential of such procedures. These prostheses ultimately fell out of favour owing to poor long-term success rates, pelvic pain, infections and the emergence of the AUS. Four major developments have subsequently renewed our enthusiasm for slings in the treatment of PPI: the evolution of synthetic sling materials leading to the production of the woven polypropylene mesh sling, the favourable experiences in using these mesh slings for the treatment of stress urinary incontinence in women, the development of bone anchors and the increasing familiarity with transobturator techniques for sling passage.

The bone-anchored woven polypropylene mesh sling, particularly the InVance sling introduced in 2000 (American Medical Systems, Inc.) is presently the most commonly implanted (Fig. 1). This material has been extensively used in the treatment of stress incontinence in women, with exceedingly low rates of infection and erosion. The mesh was adapted for placement in men by weaving it into a stiffer and thicker sheet to allow for more robust compression of the bulbar urethra. It is placed outside the subcutaneous fatty tissue overlying the bulbocavernosus muscle to further minimize the risk of erosion. The development of titanium bone screws to anchor the mesh into the pubic rami subsequently allowed the mesh to be placed through an entirely transperineal approach in a minimally invasive fashion, while allowing solid long-lasting fixation. Short- and medium-term follow-up from a number of single-centre studies are now available[15–19] and are comprehensively reviewed by Comiter[20] and by Sousa-Escandon and colleauges.[21] Cure rates range from 37% to 87%, cure or improved rates from 64% to 100% and satisfaction rates are typically 70% to 80%. The longest prospective study to date comes from Comiter,[15] who evaluated 48 patients with a median follow-up of 48 months: 65% of these patients were cured (pad-free) and 80% were cured or much improved. Patients with more severe incontinence tend to do worse with slings (as with all anti-incontinence procedures), and patients who had prior radiation therapy also fare worse, owing to a less compressible urethra.[17,22] Complications from implantation of the bone-anchored woven polypropylene mesh sling have tended to be minor and short-lived. Infection rates are typically about 2%, and erosion and atrophy are not reported. The most common complication is scrotal pain or numbness, which affects 16% of patients or more, but typically resolves within 3 months.[15,17] As long as detrusor contractility is not significantly impaired, the sling does not appear to significantly obstruct voiding.[23] In the event of sling failure, it can be tightened, or an AUS can be implanted, either distal to the intact sling or by dividing the sling (without removing it altogether).[24]

Many other slings have been described in recent years. Several authors have reported placing polypropylene mesh using sutures passed retropubically rather than fixing with bone anchors.[25–27] Although early results on small numbers appear promising, longer term follow-up suggests some loss of efficacy with time, with 30%–40% totally dry, 50%–60% socially continent and up to 27% requiring revisions.[28,29] Sousa-Escandon and colleagues[21] reported a novel adjustable sling that allows for tensioning of the sutures above the rectus fascia: at 7 months, 83% of 48 patients were dry and 8% required readjustment. Biological grafts have also been employed; however, they do not appear to provide comparable efficacy to woven polypropylene mesh.[19] Composite grafts have also been used successfully.[30,31]

American Medical Systems launched an AdVance transobturator sling in 2006, proposed to impart benefit not only via suburethral compression, but also by relocating and elevating the bulbar urethra more proximally.[30] Early experience has suggested continence rates of only 40% with this approach, and it has been suggested that the suburethral portion of the sling is too narrow, leading to kinking of the urethra with subsequent voiding dysfunction and ongoing incontinence.[31] Early results have also now been reported for an inside-out transobturator sling.[32] Comiter and Rhee[33] have recently introduced the "ventral urethral elevation plus" sling, which uses a wider based mesh with 2 arms passed through the obturator foramen and 2 more passed retropubically.

The evidence above suggests that suburethral slings can be effective in managing PPI caused by intrinsic sphincter deficiency. In particular, they appear to be most efficacious in men with mild to moderate leakage (1–4 pads per day) and in those without prior radiotherapy. In men with prior

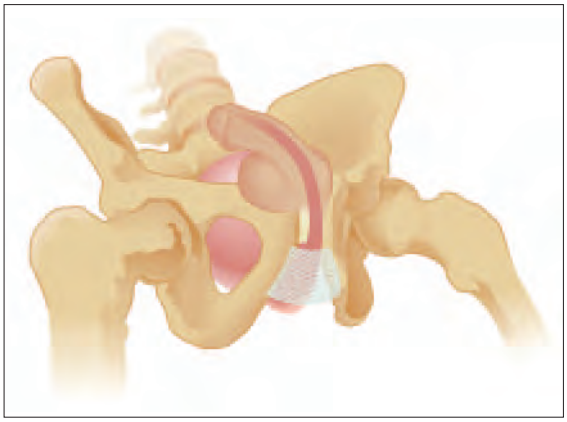

Fig. 1. The suburethral bone-anchored woven polypropylene mesh sling.

radiotherapy, an AUS should be offered. For those men with milder leakage, slings have the advantages of being implantable in a minimally invasive manner as outpatient surgery and of having no dynamic parts requiring any demand on the user. We must recognize that, because some fixed urethral resistance is imparted, prospective patients should have some detrusor contractility and be able to empty completely.[23]

In summary, early work in the 1960s and 1970s by pioneers in the field focused on fixed urethral compression to manage PPI caused by intrinsic urethral deficiency. A number of techniques were employed that demonstrated promise of this approach; however, efficacy was challenged by the limits of the materials available and an inability to fix the devices in place with sufficient resistance. As a result, urologists steered toward dynamic compression devices and the AUS was developed. With over 30 years of experience with the device, however, we have come to recognize several shortcomings of this approach. The evolution of mesh sling materials, and the development of bone anchoring and transobturator techniques have allowed us to revisit the use of suburethral slings for the treatment of PPI. These advances have permitted slings to be placed in a minimally invasive manner and fixed in position so as to create adequate resistance to leakage without obstructing voiding. Morbidity is minimal, and no moving parts are required that require user interaction or that can fail with time. In the event of inadequate efficacy, the sling can be adjusted or an AUS can be placed.

Long-term large-scale data on newer suburethral sling techniques is admittedly lacking, and as long as the field continues to fervently evolve with advances in technology and technique, we will have to be patient as this target moves on us. In the meantime, with over 15 000 InVance and 6000 AdVance slings already implanted (Matt Monarski, Senior Global Product Manager, Male Continence, American Medical Systems, Inc.: personal communication, 2008), these procedures have clearly already established themselves as a first-line therapy for PPI in many centres, and urologists worldwide have found a comfort level with these approaches. Indeed, suburethral mesh slings should be considered the primary procedure of choice for men with documented mild to moderate stress incontinence following prostatectomy, reserving artificial sphincters for those with more severe incontinence, those with poor bladder contractility and those who have experienced sling failure. Presently, the literature favours bone-anchored polypropylene slings, and other slings will continue to be evaluated in trials. While we await longer term data, urologists are encouraged to familiarize themselves with these procedures, critically evaluate their results and share their experiences in an open dialogue with the community at large.

Clinical lecturer, Division of Urology, Department of Surgery, University of Calgary, Calgary, Alta.

This article has been peer reviewed.

Competing interests: None declared.

References

1. Elliott DS, Barrett DM. Mayo Clinic long-term analysis of the functional durability of the AMS 800 artificial urinary sphincter: a review of 323 cases. *J Urol* 1998;159:1206-8.
2. Litwiller SE, Kim KB, Fone PD, et al. Post-prostatectomy incontinence and the artificial urinary sphincter: a long-term study of patient satisfaction and criteria for success. *J Urol* 1996;156:1975-80.
3. Petrou SP, Elliott DS, Barrett DM. Artificial urethral sphincter for incontinence. *Urology* 2000;56:353-9.
4. Gousse AE, Madjar S, Lambert MM, et al. Artificial urinary sphincter for post-radical prostatectomy urinary incontinence: long-term subjective results. *J Urol* 2001;166:1755-8.
5. Montague DK, Angermeier KW. Postprostatectomy urinary incontinence: the case for artificial urinary sphincter implantation. *Urology* 2000;55:2-4.
6. Raj GV, Peterson AC, Toh KL, et al. Outcomes following revisions and secondary implantation of the artificial urinary sphincter. *J Urol* 2005;173:1242-5.
7. Lai HH, Hsu EI, Teh BS, et al. 13 years of experience with artificial urinary sphincter implantation at Baylor College of Medicine. *J Urol* 2007;177:1021-5.
8. Dalkin BL, Wessells H, Cui H. A national survey of urinary and health related quality of life outcomes in men with an artificial urinary sphincter for prost-radical prostatectomy incontinence. *J Urol* 2003;169:237-9.
9. Fulford SC, Sutton C, Bales G, et al. The fate of the 'modern' artificial urinary sphincter with a follow-up of more than 10 years. *Br J Urol* 1997;79:713-6.
10. Berry JL. A new procedure for correction of urinary incontinence: preliminary report. *J Urol* 1972;85:771.
11. Kaufman JJ. Urethral compression operations for the treatment of post-prostatectomy incontinence. *J Urol* 1973;110:93-6.
12. Raz S, Kaufman JJ. Pathophysiology of the urethral compression operation: the use of silicone gel prostheses. *J Urol* 1976;115:435-8.
13. Kaufman JJ, Raz S. Urethral compression procedure for the treatment of male urinary incontinence. *J Urol* 1979;121:605-8.
14. Kishev S, Blakely G, Sanford, E. Experience with Kaufman's operation for correction of post-prostatectomy urinary incontinence (sagging urogenital diaphragm — a theory for the cause of incontinence). *J Urol* 1972;108:772-7.
15. Comiter CV. The male perineal sling: intermediate-term results. *Neurourol Urodyn* 2005; 24:648-53.
16. Rajpurkar AD, Onur R, Singla A. Patient satisfaction and clinical efficacy of the new

perineal bone-anchored male sling. *Eur Urol* 2005;47:237-42.
17. Castle EP, Andrews PE, Itano N, et al. The male sling for post-prostatectomy incontinence: mean followup of 18 months. *J Urol* 2005;173:1657-60.
18. Gallagher BL, Dwyer NT, Gaynor-Krupnick DM, et al. Objective and quality-of-life outcomes with bone-anchored male bulbourethral sling. *Urology* 2007;69:1090-4.
19. Giberti C, Gallo F, Schenone M, et al. The bone-anchor sub-urethral sling for the treatment of iatrogenic male incontinence: subjective and objective assessment after 41 months of mean follow-up. *World J Urol* 2008;26:173-8.
20. Comiter CV. Surgery insight: surgical management of prostprostatectomy incontinence — the artificial urinary sphincter and male sling. *Nat Clin Pract Urol* 2007;4:615-24.
21. Sousa-Escandon A, Cabrera J, Mantovani F, et al. Adjustable suburethral sling (Male Remeex System®) in the treatment of male stress urinary incontinence: a multicentric European study. *Eur Urol* 2007;52:1473-80.
22. Fischer MC, Huckabay C, Nitti VW. The male perineal sling: assessment and prediction of outcome. *J Urol* 2007;177:1414-8.
23. Ulrich NF, Comiter CV. The male sling for stress urinary incontinence: urodynamic and subjective assessment. *J Urol* 2004;172:204-6.
24. Fisher MB, Aggarwal N, Vuruskan H, et al. Efficacy of artificial urinary sphincter implantation after failed bone-anchored male sling for postprostatectomy incontinence. *Urology* 2007;70:942-4.
25. Migliari R, Pistolesi D, De Angelis M. Polypropilene sling of the bulbar urethra for post-radical prostatectomy incontinence. *Eur Urol* 2003;43:152-7.
26. Wadie BS. A novel technique of bulbourethral sling for post-prostatectomy incontinence. *Scand J Urol Nephrol* 2007;41:398-402.
27. Schaeffer AJ, Clemens JQ, Ferrari M, et al. The male bulbourethral sling procedure for post-radical prostatectomy incontinence. *J Urol* 1998;159:1510-5.
28. Migliari R, Pistolesi D, Leone P, et al. Male bulbourethral sling after radical prostatectomy: intermediate outcomes at 2 to 4-year followup. *J Urol* 2006;176:2114-8.
29. Stern JA, Clemens JQ, Tiplitsky SI, et al. Long-term results of the bulbourethral sling procedure. *J Urol* 2005;173:1654-6.
30. Rehder P, Gozzi C. Transobturator sling suspension for male urinary incontinence including post-radical prostatectomy. *Eur Urol* 2007;52:860-6.
31. Klingler HC, Marberger M. Incontinence after radical prostatectomy: surgical treatment options. *Curr Opin Urol* 2006;16:60-4.
32 Leval J, Waltregny D. The inside-out trans-obturator sling: a novel surgical technique for the treatment of male urinary incontinence. *Eur Urol.* Epub 2007 Nov 20 ahead of print.
33. Comiter CV, Rhee EY. The "ventral elevation plus" sling: a novel approach to treating stress urinary incontinence in men. *BJU Int* 2007;101:187-91.

Correspondence: Dr. Kevin Carlson, 417-1011 Glenmore Trail SW, Calgary AB T2V 4R6; kvc3@hotmail.com