The artificial urinary sphincter is the treatment of choice for post–radical prostatectomy incontinence

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In 1973, an innovative implantable surgical device for urinary incontinence was first introduced.[1] From the first publication, through the last major modification of the narrow-back cuff design in 1985,[2] and up to today the artificial urinary sphincter (AUS) is still the most frequently used and reported surgical treatment for male urinary incontinence. More is known about the AUS than about any other interventional treatment for postprostatectomy incontinence (PPI). Durability, adverse factors, use in elderly patients and revisional surgery are reported extensively.

Reported results

The AUS has the longest track record of success and the largest numbers of patients reported compared with any other treatment. In 1997, Leibovich and Barrett[3] reported on the experience from the Mayo Clinic in 458 patients and reviewed the literature comprising another 519 patients, half of whom had undergone the procedure for PPI. The overall continence rate was 88%, revision rate was 23%, mechanical reliability was 88% and satisfaction rate was greater than 90%. In 1999, Hajivassiliou[4] analyzed reports of 2606 patients from 1985 to 1993 and reported that improvement was seen in 88% and continence was achieved in 73%. The global revision rate was 32% and the overall majority (> 85%) required only 1 revision. He also reviewed the Food and Drug Administration's database of 17 000 to 20 000 devices. There were 4130 audited complications for 3508 patients representing a rate of 20%–25%. The Food and Drug Administration also published a report on the AUS[5] and reviewed 67 articles published between 1985 and 2000 comprising 4127 patients. They examined 12 173 patient information forms from the manufacturer showing a 5-year revision-free rate of 75%. They also reviewed the results of a 323-patient retrospective study showing an 84% probability of device use for 9 years. Furthermore, an 85-patient prospective study showed a 2-year revision rate of 17%.

Table 1. Results of the artificial urinary sphincter in post–radical prostatectomy incontinence

Author(s)	No. of patients	Follow-up, yr	0–1 pads/day, %
Montague [8]	66	3.2	75
Perez and Webster [6]	49	3.7	85
Martins and Boyd [9]	28	2.0	85
Fleshner and Herschorn [10]	30	3.0	87
Mottet et al [11]	96	1.0	86
Madjar et al [12]	71	7.7	59
Klijn et al [13]	27	3.0	81
Haab et al [14]	36	7.2	80
Trigo Rocha et al[15]	40	4.5	90
Kim et al.[16]	124	6.8	82
Lai et al.[17]	218	3.1	69
Goldwasser et al.[2]	42	1.2	82

Reported results have been consistent. Success rates for AUS as defined by a continence status of 0 to 1 pads per day range from 59% to 90%,[6,7] as shown in Table 1.[2,6,8–17] Just as with reported rates of incontinence following prostate cancer surgery depend on the definition of incontinence, continence rates with the AUS can vary with the definition of continence, the method of evaluation and the length of follow-up. The lowest rates are from patient-administered questionnaires. Pad-free rates range from 10% to 72%.[9,18–22] Nevertheless, high satisfaction rates of 87% to 90% are consistently reported, even without total continence.[10,14,18]

The AUS has also been reported to have a positive impact on health-related quality of life.[10,14,18]

Durability

One potential downside of the AUS is the need for periodic revisions in a number of patients. Revision

and explantation rates due to mechanical failure, urethral atrophy, infection and erosion vary considerably among studies with reports of 8%–45% and 7%–17%, respectively.[22] In a large cohort reported by Lai and colleagues,[17] nonmechanical failure had decreased from 17% to 9% and mechanical failure had decreased from 21% to 8% following introduction of the narrow-back cuff. Mean time to reoperation was 26.2 (mean 2–68) months. With a Kaplan–Meier analysis, the overall 5-year expected product survival was 75%. Only 6% of devices failed mechanically, at an average of 68.1 months, with 75% of patients requiring no revisions at 5 years. Actuarial freedom from revision at 5 years was estimated at 50%–75%.

Venn and colleagues[23] analyzed the outcome of 100 patients in whom an AUS had been implanted for more than 10 years. Thirty-six percent of patients still had the original sphincter and were continent at a median follow-up of 11 years. The bulbar cuff, as compared with the bladder neck cuff, provided a slightly better continence rate at 10 years, 92% and 84%, respectively. The lowest erosion rate occurred with the bulbar cuff. Device survival rate at 10 years was 66% in this series.

The long-term efficacy of the AUS was also demonstrated by Fulford and colleagues[24] who reported that at 10–15 year follow-up 75% of patients with an implanted AUS either still had or died with a functioning device. There are more reports showing long-term efficacy at 6–11 years.[22–25] Furthermore, Raj and colleagues[26] demonstrated long-term durability even after revisional surgery.

AUS after radiotherapy

Previous radiotherapy to the pelvis is not a contraindication for AUS placement in men,[25] as the ultimate outcome seems to be similar whether or not they have received radiation therapy,[27] although a higher incidence of urethral atrophy, erosion and infection requiring surgical revision has been reported in irradiated patients compared with those not irradiated (41% v. 11%). Despite this observation, long-term continence and patient satisfaction appear to not be adversely affected in the irradiated male patient.[27] (Reported revision rates and continence outcomes are shown in Table 2.[6,7,9,17,20,28–30])

AUS in elderly men

Age is not a contraindication to the use of the AUS provided the patient is cognitively intact and has sufficient manual dexterity. O'Connor and colleagues[31] reported a success rate of 72% in 29 men with a mean age of 77.6 years and a mean follow-up of 5 years after implantation. Thiel and colleagues[32] reported a success rate (≤ 1 pad/d) of 83% in 86 men with a mean age of 72 years. Furthermore, the device can be easily deactivated if the elderly patient is no longer able to operate the sphincter.

Revisional surgery

Erosion and infection are 2 major complications that almost invariably necessitate removal of the prosthesis. Most recent large series report an incidence

Table 2. The artificial sphincter for incontinence after radiotherapy

Study	No. of radiotherapy patients	Revision rate after radiotherapy, %	Continence, %
Martins and Boyd[9]	34/81	51 (v. 49% for the no radiotherapy group)	88 (v. 94% for the no radiotherapy group)
Wang and Hadley[28]	16	25 (infection and erosion 12.5%)	87
Perez and Webster[6]	11/75	55	63
Gundian et al.[29]	15/56	22	90
Elliott and Barrett[20]	46/313	22	—
Manunta et al.[30]	15/72	53 (infection and erosion 20%)	73
Gomha and Boone[7]	28/86	25 (similar to a no radiotherapy control group)	64
Lai et al.[17]	60/176	20 (v. 32% for the no radiotherapy group)	69

of infection and erosion of generally less than 8%.[15–17,33–37] As would be expected, the highest incidence has been reported with the longest follow-up (10–15 yr).[8]

Recurrent incontinence may be due to alteration in bladder function (overactivity), urethral atrophy or mechanical malfunction. Bladder overactivity, which is usually unrelated to the AUS, can frequently be treated with anticholinergics and conservative measures.

Urethral atrophy may occur at the cuff site secondary to long-term mechanical compression of the periurethral and urethral tissues. The incidence of urethral atrophy leading to revision varies from 3% to 9%.[3,8,14,17,38–41] The incidence of atrophy can be lessened with nocturnal deactivation of the cuff.[42] Revisions may include balloon pressure elevation,[9] cuff replacement, repositioning or downsizing because of urethral atrophy,[43] a second or tandem cuff,[44,45] or transcorporal cuff placement.[46]

Mechanical malfunction includes perforation of one of the components with loss of fluid from the system, air bubbles or organic debris within the system causing inadequate function of the pump, disconnection of the tubes or kinking of the tubes. Introduction of "kink-free" tubing has virtually eliminated this last complication. The incidence of these complications varies widely, ranging from 0%[39] to 53%[24] with the longest follow-up. In this latter study, the cuff seemed to be the most vulnerable part of the system (22 cuff failures in 18 patients, most of them occurring during the first 2 to 3 years following implantation), followed by pump failure (6 times in 4 patients). Blockage is an exceptional event, occurring only once in 61 patients followed from 10 to 15 years.[24] In the most recent publication from the Baylor College of Medicine chronicling a 13-year experience with the AUS,[17] mechanical failure occurred at an average of 68.1 months postoperatively.

Long-term efficacy and durability can still be expected following revisional surgery.[26]

Conclusion

Other interventional treatments such as injectable agents, implantable balloons and the male sling for PPI are available. None has yet achieved the same consistency of results, numbers of patients reported and long-term durability as the AUS. Intermediate term data on limited numbers of patients may support the use of some of these treatments for mild to moderate incontinence in patients without risk factors such as radiation. However, because of the wealth of information published with consistent long-term results, the AUS remains the gold standard for the treatment of PPI secondary to sphincteric insufficiency in patients with moderate to severe incontinence.[47]

The AUS has the largest body of literature reporting long-term success. This long-term success rate and high level of patient satisfaction outweigh the need for periodic revisions in some patients. Overall, the AUS remains the reference standard to which all other treatments must be compared.

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The positions provided in the Point/Counterpoint series are presented as general information and do not necessarily reflect the personal opinions of the authors.

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