The artificial urinary sphincter. 

A new solution for incontinent patients

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SUMMARY

Treatment of urinary incontinence with the artificial urinary sphincter has been available in centres such as London and Liverpool for a number of years. This service is now available in the department of urology of the Belfast City Hospital. Twelve patients have had successful implantation of an artificial urinary sphincter for urinary incontinence, and ten are now fully continent. One patient with Wegener's granulomatosis developed active disease in his urethra which has precluded activation of the device. One patient has had the device removed because of erosion into the urethra.

INTRODUCTION

Urinary incontinence is a distressing condition which can have profound psychological effects on the patient, leading to social withdrawal and loss of self esteem. The financial consequences of conventional lifelong treatment of incontinence (pads and catheters) are enormous. The majority of patients suffering from urinary incontinence are female who usually respond to a bladder neck suspension procedure. Male patients and patients with neuropathic bladders need a more sophisticated approach to the problem 1,2.

In 1973 Scott 3 implanted the first artificial urinary sphincter and since then the device has undergone modifications to make it more reliable and easier to use. The advantage of the current model is that it can be left in a deactivated state until tissue healing is complete thus minimising the risk of device erosion. We describe our experience of 12 patients who had the American Medical Systems model 800™ (AMS 800) artificial sphincter inserted in a two year period.

PATIENTS AND METHODS

Twelve patients age range 19-76 (mean 48) have been treated. The clinical diagnosis, urodynamic findings and adjunctive surgical procedures for eleven are summarised in the table. All patients were assessed by clinical examination and endoscopy of the lower urinary tract. All patients had video urodynamics performed using the Aspen Medical, GaelTech GR 800 urodynamic system.

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Artificial Urinary Sphincter

Bladder capacity, intravesical pressure, and urethral pressure profiles were measured. The mechanics of the device were explained in detail to the patient, and those with neuropathic incontinence were shown how to perform clean intermittent self catheterisation.

The patients were admitted for preoperative bowel preparation. Triple antibiotic therapy (gentamicin, metronidazole and penicillin) is continued for five days postoperatively. In males the device can be inserted around the bulbar urethra, the membranous urethra or around the bladder neck. In the female it can only be placed around the bladder neck. The reservoir determines the pressure in the cuff and a variety of pressures (40-50, 51-60, 61-70, 71-80 cm H₂O) can be achieved using different reservoirs. (Fig 1).

![Fig 1. The artificial urinary sphincter. (a) The reservoir. (b) The pump. (c) The cuff which is inserted around the urethra or bladder neck.](image)

To implant an artificial urinary sphincter around the bulbar urethra, an incision is made in the perineum and the bulbar urethra is mobilised with the bulbospongiosus muscle. A measuring device is used to select the correct size of cuff. A second incision is made in either iliac fossa, and the reservoir is placed deep to the rectus abdominis in an extraperitoneal position. A subcutaneous tunnel is made into the scrotum, and the pump mechanism placed in a subcutaneous position. In the female the pump mechanism is placed in the labium majus. The device is filled with an isotonic radio-opaque solution taking great care not to allow any contamination of the tubing with blood or air.

If the device is placed around the bladder neck a suprapubic approach is required (Fig 2). The procedure is technically difficult as there is a risk of entering the vagina in the female or the rectum in the male. If this complication occurs the procedure must be abandoned.

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RESULTS

Eleven patients have had successful insertion of the artificial sphincter. Ten are fully continent and using the device successfully. One patient's urethra was damaged during mobilisation, and the device subsequently eroded into the urethra and had to be removed. One patient who had Wegener's granulomatosis of the prostate and bladder neck developed a dense urethral stricture three months after insertion of the artificial sphincter. The stricture was biopsied which confirmed the presence of active Wegener's granulomatosis. He is currently undergoing treatment and the sphincter has been left deactivated. He will require a urethroplasty to maintain urethral patency. One patient with spina bifida who had mild stress incontinence postoperatively has had a further procedure to insert a higher pressure reservoir and is now dry.

| Patient | Diagnosis                        | Cystometry      | Sphincter | Adjunctive procedure |
|---------|----------------------------------|-----------------|-----------|----------------------|
| 1       | Post prostatectomy               | Unstable        | Weak      | Cystoplasty          |
| 2       | Post prostatectomy               | Stable          | Weak      |                      |
| 3       | Post prostatectomy               | Stable          | Weak      |                      |
| 4       | Post prostatectomy               | Stable          | Weak      |                      |
| 5       | Post prostatectomy               | Stable          | Weak      |                      |
| 6       | Post prostatectomy               | Stable          | Weak      |                      |
| 7       | Carcinoma prostate              | Stable Small capacity | Weak  | Cystoplasty          |
| 8       | Wegener's granulomatosis        | Stable Small capacity | Weak  | Cystoplasty Urethrotomy |
| 9       | Spina bifida                    | Stable          | Weak Small capacity | Cystoplasty          |
| 10      | Spina bifida                    | Stable          | Weak      | Urethrotomy          |
| 11      | Spina bifida                    | Stable          | Weak      |                      |

Table. Details of 11 patients who have had successful insertion of an artificial urinary sphincter.
DISCUSSION

Patients selected for implantation of an artificial urinary sphincter have one of the following conditions: post-prostatectomy incontinence, failed surgery for stress incontinence, neuropathic bladder, congenital abnormalities of the urinary tract or post-traumatic injury. Careful selection is essential if optimum results are to be obtained. The patients must be highly motivated and intelligent enough to understand the workings of the device, and be prepared to undergo more than one surgical procedure to attain continence.

The artificial sphincter is designed to produce a bladder outlet resistance in the range of pressures as described above. The design of the device allows rises in intra-abdominal pressure to be transmitted to the cuff. This usually occurs relatively slowly, but if intra-abdominal pressure rises very quickly, as when getting up from a low chair, slight stress incontinence may occur. This has an important bearing on patient selection, as patients with spina bifida in wheelchairs generate high intra-abdominal pressures when trying to move themselves in the wheelchair, as do those who walk with elbow crutches. Pre-operative assessment of the patient, treatment of any urinary tract infection, dermatitis or other foci of infection is essential before inserting the device.

Patients should be prepared to perform clean intermittent self-catheterisation if necessary. This is an important part of the management of the neuropathic bladder to eliminate residual urine consequent on inefficient bladder emptying. After insertion of an artificial urinary sphincter in patients with neuropathy, or in those who have had a cystoplasty, bladder emptying may be further impaired and some patients may need to perform self-catheterisation through the sphincter cuff to eliminate residual urine.

Video urodynamics are essential to accurately measure bladder pressure, capacity and sphincter function. The anatomy of the bladder and bladder neck can be visualised and vesicoureteric reflux identified. Careful endoscopy is needed to ensure that the patient’s urethra is normal and any stricture or urethral disease should be treated before inserting the device. The bladder must be of adequate capacity to allow the patient to hold urine for a socially acceptable time. The bladder must also be capable of storing urine at low pressure in order to protect the upper renal tracts. It is imperative to treat any detrusor instability with anticholinergics. If medical treatment of instability fails then the surgical procedure of choice is an ileocystoplasty (the “clam” procedure). The “clam” ileocystoplasty involves opening the bladder like an open clamshell and suturing in a patch of ileum, which has the combined effect of increasing bladder capacity and reducing bladder pressure.

Patients with post-prostatectomy injury, or following trauma, usually have pure sphincter weakness. Patients with neuropathic disorders, those following failed stress incontinence surgery, or those with congenital abnormalities of the urinary tract are more complex and may require a variety of adjunctive procedures.

The major complication following implantation is infection leading to erosion. If this occurs, the device must be removed, as healing will not occur in the presence

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of a foreign body. Mundy\textsuperscript{2} has identified patients who are at risk for this and quotes 15\% infection erosion rate in patients with neuropathic bladders. In patients who have had a sling operation around the bladder neck or in any patient who has had pelvic radiotherapy the infection erosion rate is over 50\%. Thus, previous sling surgery or radiotherapy is a contra-indication to insertion of an artificial urinary sphincter.\textsuperscript{6,7} Erosion rates are higher in elderly patients or when the device is implanted around the bulbar urethra as opposed to the bladder neck. Although implantation around the bladder neck has a lower rate of erosion, the operative procedure is more difficult and is associated with greater morbidity. Patients with incontinence as a result of major trauma may have such extensive fibrosis at the bladder neck as to preclude implantation at this site. Erosion is also more frequent when higher pressure reservoirs are used and it is our practice to implant a low pressure reservoir initially, changing to a higher pressure if incontinence persists.

The major alternative to implantation of an artificial urinary sphincter is reconstruction of the bladder neck or a urinary diversion. Continent urinary diversions are associated with a high complication rate, with the obvious disadvantages of needing a stoma which has to be catheterised. Successful implantation of an artificial sphincter offers a better quality of life. This procedure does not have a place in the first line of treatment of stress incontinence in females and is only used for complex cases following failed anti-stress procedures.

The overall success rate of the artificial urinary sphincter is about 95\%, with 5\% being persistent failures. The major complications are infection and erosion, which occur in 10\%-15\% of patients. Two percent of the devices develop early mechanical failure and a further 2\% develop late longterm failures usually due to leakage from the cuff.

Our experience indicates that with careful patient selection excellent results can be achieved with the artificial urinary sphincter. It is the procedure of choice for patients with post-prostatectomy incontinence. It is ideal for certain patients with neuropathic bladder dysfunction who are highly motivated and have normal hand function.

REFERENCES

1. O'Flynn K J, Thomas D G. Artificial urinary sphincter insertion in congenital neuropathic bladder. \textit{Br J Urol.} 1991; 67: 155-7.
2. Mundy A R, Stephenson T P. Selection of patients for implantation of the Brantley Scott artificial urinary sphincter. \textit{Br J Urol.} 1984; 56: 717-20.
3. Scott F B, Bradley W E, Timm G W. Treatment of urinary incontinence by an implantable prosthetic sphincter. \textit{Urology.} 1973; 1: 252-9.
4. Rickwood A M K, Thomas D G, Philip N H, Spicer R D. Assessment of congenital neurovesical dysfunction by combined urodynamic and radiological studies. \textit{Br J Urol.} 1984; 54: 512-8.
5. Stephenson T P, Mundy A R. Treatment of the neuropathic bladder by enterocystoplasty and selective sphincterotomy or sphincter ablation and replacement. \textit{Br J Urol.} 1985; 57: 27-31.
6. Mundy A R. Artificial sphincters. \textit{Br J Urol.} 1991; 67: 225-9.
7. Nurse D E, Mundy A R. One hundred artificial sphincters. \textit{Br J Urol.} 1988; 61: 318-25.

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