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Treatment of Urinary Incontinence by the Scott-Bradley-Timm Artificial Sphincter

A Report of Eight Cases

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Summary. Eight patients were treated with an implantable artificial urinary sphincter. Five patients had neurogenic bladders, two had postprostatectomy incontinence and one severe recurring stress incontinence. The main problem was mechanical failure of the device in four patients. The present results (follow up two to ten months) may be classified as satisfactory in six and unsatisfactory in two patients.

Key words: Prosthetic urinary sphincter, Urinary incontinence, Bladder dysfunction.

The treatment of severe neurogenic and non-neurogenic urinary incontinence are among the most difficult problems in urology. Urinary diversion such as cutaneous uretero-ileostomy has until today been required as a last resort, especially in female patients, but at the cost of changing the patient's body image.

Prosthetic implantable devices delivering passive compression to the urethra have been used by Berry (11) and Kaufmann (2) but the success rate, especially in neurogenic incontinence, is low.

The invention of an implantable externally controllable urinary prosthesis (3, 4, 5) holds promise for the satisfactory management of many incontinence cases. We have treated eight patients by this method.

Method

The sphincter prosthesis is constructed of Medical Grade Silastic^R and is totally implantable. It consists of a cuff, which comes in two different widths (1.7 and 2.0 cm) and with circumferences ranging from 5.0 to 11.0 cm. The cuff can be placed around the bladder neck or the urethra.

Its volume can be varied by squeezing fluid from a reservoir by means of bulb-pumps that are placed high in the labia or in the scrotum (Fig. 1). The different parts are connected by Silastic^R tubing containing four valves. Two valves (V_1 and V_3) are check-valves for the direction of fluid movement, and two valves (V_2 and V_4) control pressure. Valve no. 4 is by far the most important since it determines the pressure in the cuff - usually 75-100 cm of water.

Continence is obtained by compressing the right inflation bulb-pump which allows the fluid in the system (Hypaque^R 25 %) to pressurize the cuff. Excess fluid drains through valve no. 4 back to the reservoir. When micturition is desired the deflation bulb placed on the left side is compressed which will empty the cuff and relieve pressure on the urethra.

The operative procedure has been described by Scott et al. (3). During operation the pressure in the cuff is measured during activation of the system.

Activation of the sphincter starts as soon

as local tenderness allows usually on the third postoperative day.

Fig. 2 shows the artificial sphincter as seen radiologically.

Material

Eight patients have been treated by this method in three different institutions.

Five patients had neurogenic bladder of the infranuclear type, two had postprostatectomy incontinence and one severe gynaecological stress incontinence.

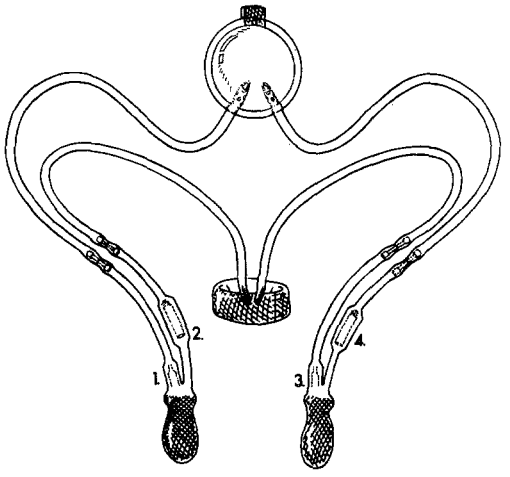

Fig. 1. The artificial urinary sphincter consists of four main parts: a reservoir (top), a cuff, inflating mechanism and deflating mechanism. In the tubing there are four valves (shown with numbers 1-4)

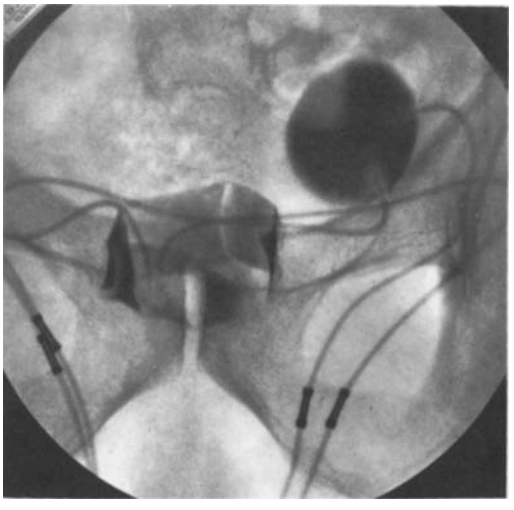

Fig. 2. The radiological appearance of the artificial urinary sphincter

The age, sex and diagnosis are presented in Table 1.

Table 2 shows previous urological surgery performed

Results

Continence was obtained initially in all eight cases. At present continence is perfect in six patients two to ten months after implantation. One patient with myelodysplasia has developed detrusor hyperreflexia three months postoperatively. This leads to leakage of urine and is proving difficult to control pharmacologically. Another patient is moderately incontinent following two repairs and subsequent fibrosis around the cuff. There have been six mechanical failures of the prosthesis in four patients. Reoperation and replacement of the defective parts lead to a good result in three cases. Table 3 shows these complications. No wound infection was encountered but four patients, all in the neurogenic group, have had one postoperative urinary infection.

Discussion

Before accepting a patient as a candidate for the Scott-Bradley-Timm continence prosthesis the following conditions should be fulfilled:

1. The patient should be cooperative and intellectually capable of understanding the principle of treatment.
2. The patient should have sufficient dexterity to control the apparatus.
3. The cystometrogram should not show uninhibited contractions.
4. The bladder outflow tract should be satisfactory and residual urine low.
5. There should be no urinary tract infection, decubitus ulcers or genital skin lesions.

This method is the first to allow the restoration of continence by a mechanical implant which is externally controllable. All together 250 cases have been treated by this method, for the major part in Houston, Texas, by Scott (3, 4). The four major complications are wound infection, urethral pressure necrosis with urinary extravasation, development of detrusor hyperreflexia and mechanical device failure. In the present series only the latter two have been seen.

Wound infection will almost certainly require removal of the foreign body in order to allow the infection to resolve.

Urethral pressure necrosis is not seen if the pressure in the cuff maintains the recommended level. Peroperative pressure measure-

ment is therefore a very important part of the procedure.

Detrusor hyperreflexia should not be present in the patient accepted for operation but it may develop postoperatively. The reason for this remains obscure. The presence of the cuff may induce the problem by setting up a reflex arc via the sacral medulla or the fact that the bladder then fills to capacity, in contrast to the situation in the totally incontinent, which may unmask a latent hyperreflexia.

In the present series mechanical device failure has been the main problem. Two reservoirs have been exchanged. In one case external trauma was probably the reason, in another there was a defect in the Silastic^{R} material. Both ruptures occurred in patients equipped with an early type of reservoir. Following a design change no problems with respect to the reservoir have been encountered. Five no. 4 valves have been exchanged. This valve is the most vulnerable part of the system. In four cases pressure in the cuff was too low, in one case too high. Exchange of valve no. 4

Table 1. Age, sex and diagnosis of 8 patients treated with the artificial sphincter

Pt. no.	Age/Sex	Diagnosis	Institution
1	23/♂	Op. for sacral ganglioneuroma x 2	GH
2	10/♂	Myelodysplasia lumbosacralis	GH
3	10/♀	Myelodysplasia lumbosacralis	GH
4	63/♂	Prostatectomy	KH
5	54/♀	Stress incontinence	MH
6	62/♂	Prostatectome	MH
7	9/♂	Myelodysplasia lumbosacralis	GH
8	44/♂	Fracture of T. 12	GH

GH: Gentofte Hospital; KH: Karolinska Hospital; MH: Mejlans Hospital.

Table 2. Previous relevant surgery in 8 patients treated with the artificial sphincter

Pt. no.	Age/Sex	1°	2°	3°	4°
1	23/♂				
2	10/♂	Transurethral ext. sphincterotomy			
3	10/♀				
4	63/♂	Prostatectomy			
5	54/♀	Vaginal hysterectomy	Ant. vaginal repair	Lig. rotundum plasty (Kasdon)	TUR
6	62/♂	Retropubic Prostatectomy	TUR	Kaufmann II	
7	9/♂	Transurethral ext. sphincterotomy			
8	44/♂	TUR	TUR	TUR	TUR

Table 3. Technical complications following implantation of artificial sphincter

Pt. No.	Age/Sex	1°	2°	Follow up months	Remarks
1	23/♂	4 months. Reservoir rupture. Malfunctioning V_4. Too large cuff.	8 months. Cuff failure	10	Continence improved but not perfect.
2	10/♂	6 months. Reservoir rupture. Malfunctioning V_4	9 months. Inflate bulb + cuff rupture Malfunctioning V_4	10	Continence perfect.
3	10/♀			6	Developed detrusor hyperreflexia postop.
4	63/♂	2 weeks. Malfunctioning V_4		6	Continence perfect
5	54/♀	3 months. Malfunctioning V_4		6	Continence perfect.
6	62/♂			4	Continence perfect.
7	9/♂			4	Continence perfect.
8	44/♂			2	Continence perfect but large residual urine

was in three instances made together with exchange of leaking sections of the system. Blood clots and lint from operation sheets may block this valve, but are almost impossible to detect during reoperation. Four cuffs have been exchanged in two patients due to either being of the wrong size (two) or material defect (two). One patient has had the inflation bulb replaced due to fluid leak. All leaks from the system have occurred at points where different primary parts are glued together.

Recurring incontinence is due to either 1. detrusor hyperreflexia or 2. mechanical device failures.

Differential diagnosis is based on cystometry, measurement of the urethral closure pressure profile, plain X-ray of the prosthesis area and peroperative X-ray with additional contrast and intraprosthetic pressure measurements.

Two to ten months after surgery 75% of the patients have perfect continence (Table 3). But improvement in prosthesis technology and selection methods will probably improve this figure.

As a conclusion it can be stated that this procedure is the only practical method of restoring continence in a number of urological invalids and still maintain voiding through the urethra. The present stage of development is still burdened by technical problems.

It is too early to forecast how durable the prosthesis is. The first implant was performed in July 1972 and is still functioning.

The cost of the prosthesis is high (approx. $1350) but this expense should be viewed against the cost inherent in conservative treatment and the social and hygienic disability which severely restricts these patient's daily lives.

The method should be used only in specialized departments where sufficient investigations can be done pre-, per-, and postoperatively in order to secure adequate evaluation of the patient and the function of the prosthesis.

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