Evolution of implanted devices for urinary incontinence[1]

Drogo K. Montague, M.D.

Prosthetic devices have been developed for management of severe urinary incontinence, which is usually not well treated with operations using host tissues. Early prostheses consisted of passive, compressive devices for the male bulbous urethra. In 1972, Scott and associates developed a hydraulic, artificial urinary sphincter (AS 721) which was implantable both in the male and female patient. Since then, design modifications have resulted in the AS 761, AS 742, AS 791, AS 792, and AS 800 models. The evolution of these devices is reviewed

Index terms: Prostheses, urinary • Urinary incontinence

Cleve Clin Q 51:405–409, Summer 1984

Bruce H. Stewart, M.D., was attracted to many problems in urology during his long and productive career. During my residency (1968–1973), Bruce was particularly interested in the treatment of severe urinary incontinence. His enthusiasm for this subject was contagious, and when I joined the urology staff in 1973, he encouraged me to work with him on new treatment methods for incontinence, an area he later generously permitted me to develop on my own.

Urologists have long known that most severely incontinent patients are not well managed by operative procedures using host tissues. Thus, it is not surprising that prosthetic devices have been devised as possible solutions for this difficult problem.

[1] Department of Urology (D.K.M., Head, Section of Urodynamics and Prosthetic Surgery), The Cleveland Clinic Foundation. Submitted for publication Dec 1983; accepted Jan 1984. jw

0009-8787/84/02/0405/05/$2.25/0

Fig. 1. Rosen prosthesis. The scrotal reservoir pump is deflated, and the balloon, which compresses the urethra, is inflated.

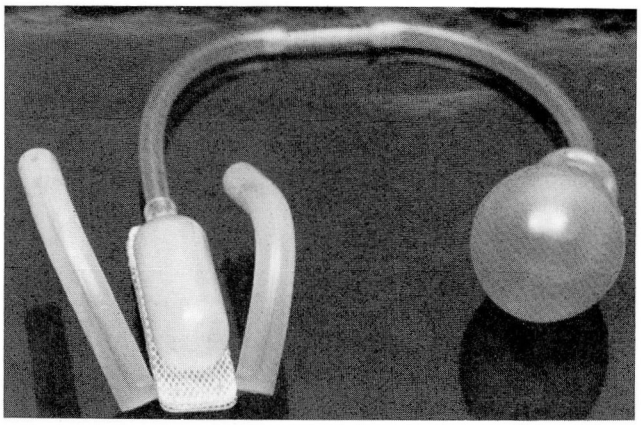

Fig. 2. Rosen prosthesis. The compression balloon is deflated for micturition.

Bulbous urethral compression devices

In 1961, Berry[1] described an acrylic prosthesis that he had developed for implantation between the bulbous urethra and the bulbocavernosus muscles of the male. The early results were encouraging, but late results were disappointing, primarily because of dislocation of the prosthesis.

In the early 1970s, Kaufman[2,3] attempted to produce compression of the male bulbous urethra without using a prosthesis by detaching and crossing the penile crura over the bulbous urethra. Subsequently, he found that it was better to leave the penile crura attached proximally and mobilize and tie them together with a Marlex band over the bulbous urethra. Later, pressure could be increased on the underlying bulbous urethra by inserting a wad of Marlex beneath the banded crura. To produce more effective compression, Kaufman[4] developed a silicone gel prosthesis which was applied against the male bulbous urethra. Straps from this prosthesis were wrapped around the crura, and later additional straps were stapled to the pubic rami. Although Kaufman abandoned his original intention of avoiding the use of prosthetic material, the silicone gel prosthesis did provide better control of incontinence. Like other passive compression procedures, this prosthesis was designed to produce enough pressure against the bulbous urethra to achieve continence, yet allow the patient to empty his bladder. If insufficient pressure were applied, however, continence was not restored, and too much pressure prevented voiding, or worse, caused necrosis of the underlying urethra.

In 1976, Rosen[5] described a bulbous urethral compression device that could be inflated and deflated by the patient. Constructed of silicone elastomer, this device had an inflatable, oblong balloon which was implanted against the bulbous urethra. Attached to the balloon were two arms encircling the opposite side of the urethra. Tubing connected the balloon to a fluid reservoir-pump which was implanted subcutaneously in the scrotum. To apply pressure against the urethra, fluid could be transferred to the balloon by squeezing the scrotal reservoir-pump (*Fig. 1*). A check valve held the fluid in place. When the patient wished to urinate, he could apply pressure to unseat the check valve, allowing the fluid to return from the balloon to the reservoir-pump (*Fig. 2*). This prosthesis resembled the Kaufman silicone gel prosthesis, except that it could be inflated and deflated at will to permit easier micturition. It was limited to use in males, and pressure in the balloon was not subject to precise control.

Artificial urinary sphincters

Earlier, in 1973, Scott and associates[6] had described a new artificial urinary sphincter, the AS 721. This hydraulic device, constructed of medical-grade silicone elastomer and stainless steel (*Fig. 3*), consisted of a circumferential sphincter cuff that could be implanted around the male or female bladder neck or around the male bulbous urethra. This cuff was connected to inflation and deflation bulbs which were implanted subcutaneously in the right and left scrotum or labia majora. The inflation and deflation bulbs, in turn, were connected to a fluid reservoir which

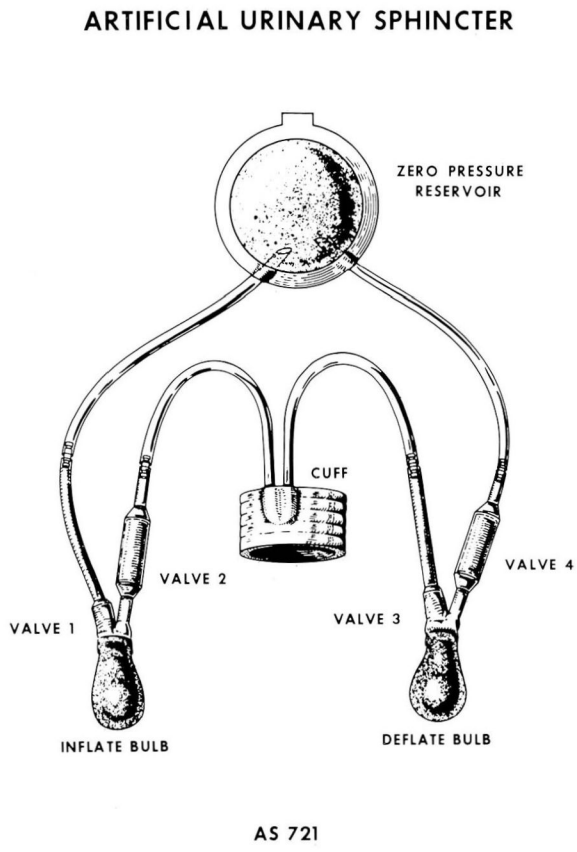

Fig. 3. Model AS 721 of the artificial urinary sphincter. [Figure 3 from Montague DK: The Scott-Bradley-Timm artificial urinary sphincters. J Urol 1981; 125: 796–798. By permission of the authors and publisher.]

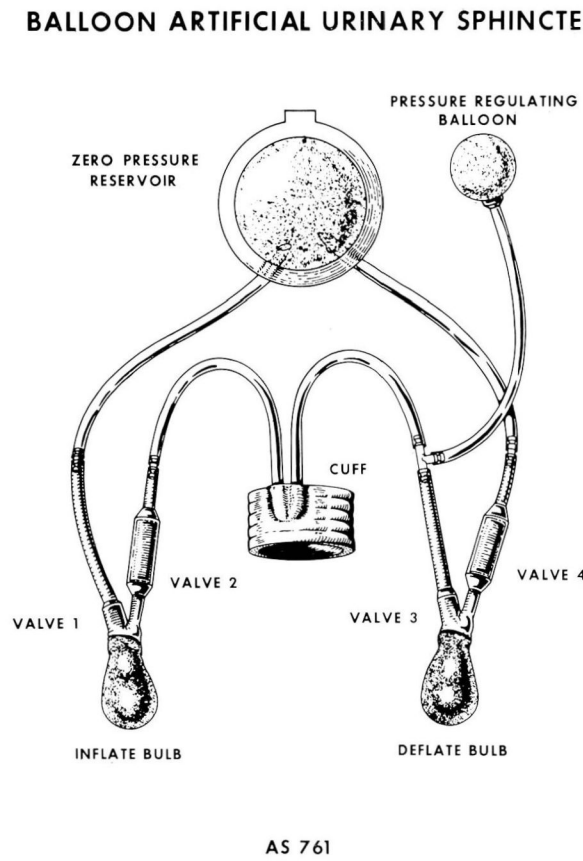

Fig. 4. Model AS 761 of the artificial urinary sphincter. [Figure 4 from Montague DK: The Scott-Bradley-Timm artificial urinary sphincters. J Urol 1981; 125:796–798. By permission of the authors and publisher.]

was implanted beneath one of the lower abdominal rectus muscles. The device was filled with isotonic saline or isotonic radiographic contrast fluid. Pressure in the sphincter cuff was controlled by a mechanical V-4 valve located above the deflation bulb.

To void, the patient squeezed the deflation bulb in the left scrotum or labium majus. Fluid in the deflation bulb was returned to the fluid reservoir. Re-expansion of the deflation bulb withdrew fluid from the sphincter cuff. Repetitive squeezing and releasing of the deflation bulb transferred fluid from the cuff back to the fluid reservoir. When the cuff was empty, the deflation bulb remained collapsed.

Following micturition, the patient reinflated the artificial sphincter by repeatedly squeezing and releasing the inflation bulb in the right scrotum or labium majus. Each squeeze of the inflation bulb sent the fluid in the bulb to the sphincter cuff. The bulb re-expanded by drawing fluid from the fluid reservoir. This process could be repeated indefinitely. When pressure in the cuff exceeded that set by the V-4 valve, the fluid returned to the fluid reservoir through the V-4 valve on the deflation side. With experience, the patient found the minimum number of squeezes of the inflation bulb required for continence.

To avoid tissue necrosis, pressures in the sphincter cuff were set by the V-4 valve below tissue perfusion pressures. This pressure maintained continence in many circumstances, but significant physical activity could cause bladder pressure to exceed sphincter cuff pressure. However, because the compressible fluid reservoir was implanted beneath the lower abdominal rectus muscles, pressure in the fluid reservoir could also rise with physical activity, thus preventing expression of fluid from the sphincter cuff into the reservoir. The AS 721 prosthesis thus represented the first physiologic approach to the restoration of urinary continence.

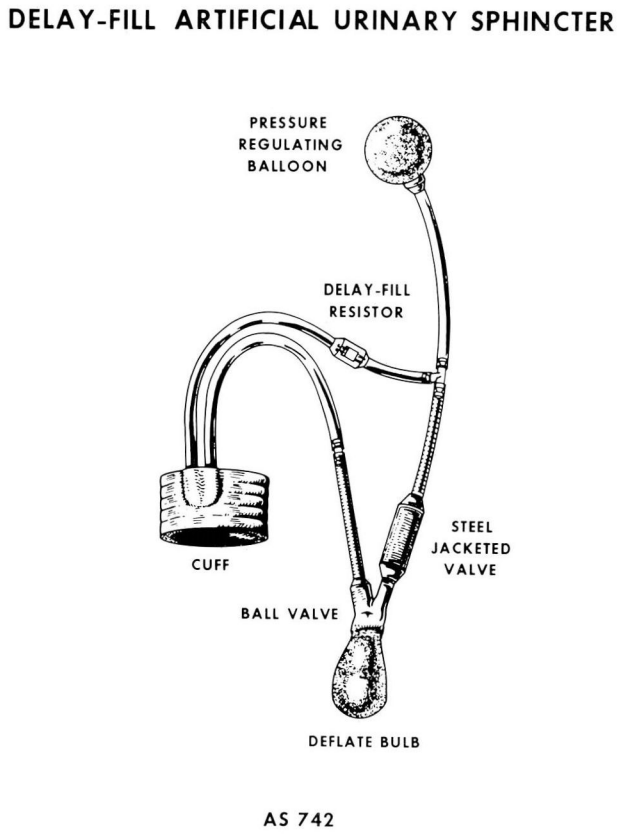

Fig. 5. Model AS 742 of the artificial sphincter. [Figure 5 from Montague DK: The Scott-Bradley-Timm artificial urinary sphincters. J Urol 1981; 125:796–798. By permission of the authors and publisher.]

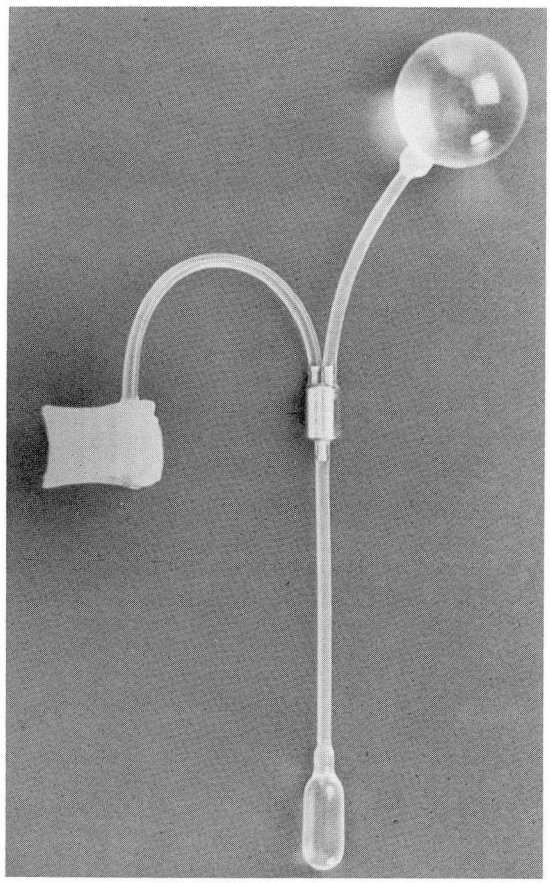

Fig. 6. Model AS 792 of the artificial urinary sphincter.

The mechanical V-4 valve was critical to the success of the AS 721 device; however, because of occasional failures, the AS 761 was devised (*Fig. 4*). This device introduced a pressure-regulating balloon between the cuff and the V-4 valve. Pressure in the balloon (and in the sphincter cuff) was controlled by the thickness of the silicone elastomer wall of the balloon and by fluid volume in the balloon.

Eventually, it became evident that this balloon could serve as both a pressure-regulating device and as a reservoir for the cuff fluid during micturition. The balloon could also provide automatic refill of the sphincter cuff following micturition. The development of the AS 742 eliminated the fluid reservoir and the inflation bulb (*Fig. 5*). Addition of a delay-fill resistor between the balloon and the sphincter cuff slowed return of fluid from the balloon to the cuff, thus giving the patient enough time to empty his bladder.

The development of AS 791 and AS 792 represented a streamlining of the AS 742 device. The AS 791 was a bulbous urethral cuff implant, and the AS 792 was a bladder neck cuff implant (*Fig. 6*). In both devices, the valves immediately above the deflation bulb and the delay-fill resistor were transferred to the interior of a stainless steel assembly to which the balloon, the cuff, and the deflation pump could be attached. Tubes from the deflation bulb and the cuff were reduced from two to one in both. Furthermore, the silicone elastomer portions of the prosthesis were now being dip-coated to eliminate seams that might be prone to fluid leaks.

A shortcoming of the AS 742, AS 791, and AS 792 devices was their inability to be left in the permanently deflated or open cuff positions. To prevent bladder neck or urethral erosion in the immediate postimplantation period, Barrett and Furlow[7,8] suggested implantation with delayed activation. The prosthesis components were implanted but not connected. After primary healing, a second operation was performed to connect the balloon, pump, and cuff to activate the de-

vice. The need for two separate operations was eliminated by the development of the AS 800 device (*Fig. 7*). The AS 800 is identical in operative principle to the AS 791 and AS 792, but the valves and the delay-fill mechanisms have been moved to a housing attached to the top of the deflation bulb. Also present in this housing is a deactivation button. Elimination of the stainless steel assembly has resulted in one fewer component to implant and only two tubing connections to be made.

When the deactivation button is depressed, the AS 800 remains deactivated, and fluid cannot flow from the balloon back into the cuff. To activate the device, the deflation bulb is firmly squeezed and the deactivation button pops out. When the deactivation button is out, the device works in the same manner as the AS 742, AS 791, and AS 792 models.

At the Cleveland Clinic, we have had experience since February 1974 with the artificial sphincters developed by Scott and associates.[9] To date, 75 devices, encompassing all models of the sphincter from the AS 721 through the AS 800, have been implanted.

Our experience with the later models suggests that more than 90% of patients will have continence restored such that no external protection need be worn.

In summary, the initial prostheses for urinary incontinence were limited to compression devices for the male bulbous urethra. The development of the Rosen prosthesis enabled compression to be applied and removed at will.

The hydraulic artificial sphincter of Scott and associates has evolved through five distinct stages. The current model (AS 800) is deceptively simple in number of components and connections. This device, however, applies controlled pressure to the bladder neck or the urethra while allowing pressure changes within the system during physical activity. To operate the device, the patient need only deflate the sphincter cuff for micturition. Fluid transfer back into the sphincter cuff for continence is automatic. The device may be deactivated and left open for an extended period without resorting to additional operations.

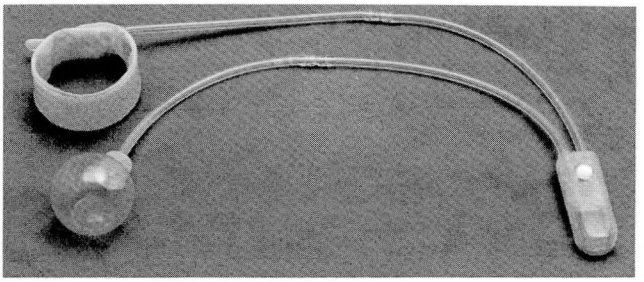

Fig. 7. Model AS 800 of the artificial urinary sphincter.

References

1. Berry JL. A new procedure for correction of urinary incontinence: preliminary report. J Urol 1961; **85**:771–775.
2. Kaufman JJ. A new operation for male incontinence. Surg Gynecol Obstet 1970; **131**:295–299.
3. Kaufman JJ. Surgical treatment of post-prostatectomy incontinence: use of the penile crura to compress the bulbous urethra. J Urol 1972; **107**:293–297.
4. Kaufman JJ. Treatment of post-prostatectomy urinary incontinence using a silicone gel prosthesis. Br J Urol 1973; **45**:646–653.
5. Rosen M. A simple artificial implantable sphincter. Br J Urol 1976; **48**:675–680.
6. Scott FB, Bradley WE, Timm GW. Treatment of urinary incontinence by implantable prosthetic sphincter. Urology 1973; **1**:252–259.
7. Barrett DM, Furlow W. Implantation of a new semi-automatic artificial genitourinary sphincter: experience with patients utilizing a new concept of primary and secondary activation. Prog Clin Biol Res 1981; **78**:375–386.
8. Furlow WL. Implantation of a new semiautomatic artificial genitourinary sphincter: experience with primary activation and deactivation in 47 patients. J Urol 1981; **126**:741–744.
9. Montague DK. The Scott-Bradley-Timm artificial urinary sphincters. J Urol 1981; **125**:796–798.