

TREATMENT OF URINARY INCONTINENCE BY IMPLANTABLE PROSTHETIC SPHINCTER*

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ABSTRACT—A completely implantable prosthetic urethral sphincter was implanted in five patients with urinary incontinence. The preliminary results indicate that this prosthesis successfully restored continence to all five patients. These patients included a forty-five-year-old woman who had persistent stress incontinence in spite of standard operative procedures, a thirty-six-year-old woman with neurologic bladder secondary to meningomyelocele, a thirteen-year-old girl with traumatic seventh-vertebra paraplegia and neurologic bladder, an eighteen-year-old man whose neurologic defect from myelomeningocele caused total urinary incontinence, and a twenty-four-year-old woman with cauda equina injury resulting in neurologic bladder dysfunction.

Attempts to cure urinary incontinence in patients with anatomic and neurologic causes of incontinence have included various operative procedures,¹⁻⁶ different prosthetic implants,⁷⁻⁹ many external appliances,¹⁰ and combinations of these procedures. Due to anatomic differences in the external genitalia, the various attempts to cure incontinence have been distinctly different in male versus female. Our preliminary results in the use of an implantable silicone rubber prosthetic urinary sphincter indicate that this new prosthesis offers volitional urinary control in both male and female patients and in various types of urinary incontinence.

This report includes five case reports of patients whose incontinence was caused by various etiological factors. At the time of this writing, all five patients, male and female, who were incontinent prior to surgical intervention are now continent.

This preliminary report is of results as of September, 1972. Since four of the five cases were patients with neurologic bladder dysfunction, control of sphincteric function by this

prosthesis may represent an important step toward complete electromechanical take-over of the micturition reflex. The combination of an electronic bladder volume sensor to correct a sensory deficit, an electrical stimulator of the detrusor muscle to achieve motor function, and an implantable prosthetic sphincter might offer new hope to the patient with severe neurologic bladder dysfunction.

Materials and Methods

The prosthetic sphincter consists of four parts: a reservoir, an inflatable cuff, and two pumps (Fig. 1A and B). The reservoir contains a fluid which can be pumped into an inflatable cuff and then back again. The inflatable cuff contains sutures in its back so that once the ends of the sutures are tied, the cuff becomes a ring encircling the urethra. Since the interior lining of the cuff is thin and elastic, inflation produces concentric pressure, like a sphincter, against the urethra.

Each pump is comprised of a bulb, two valves, and connecting tubing. The pumps are connected in parallel position between the reservoir and the cuff; compression of one bulb inflates the

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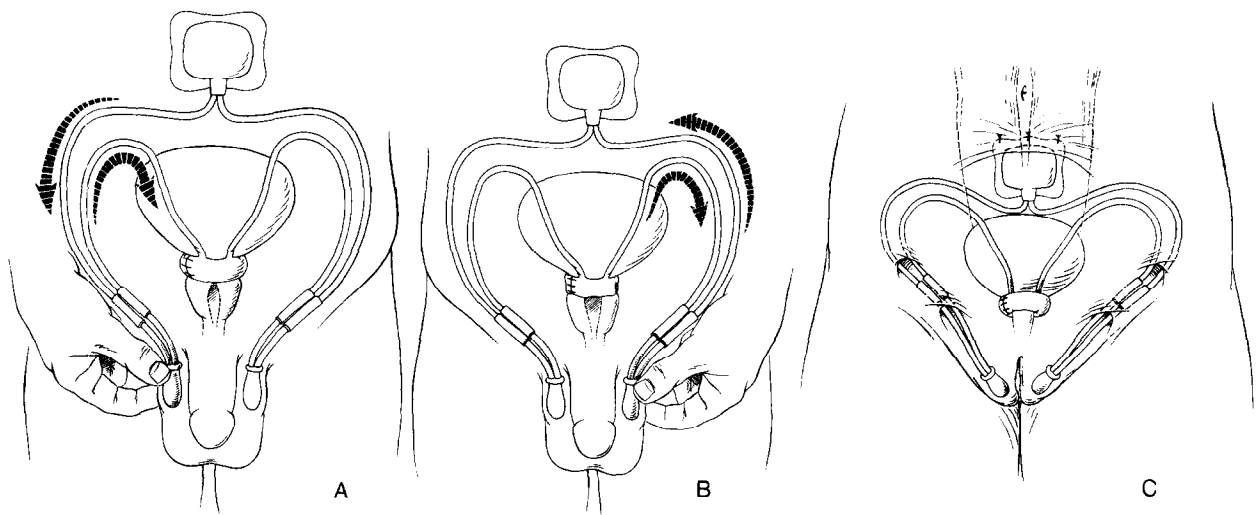


FIGURE 1. Four parts of prosthetic urinary sphincter: reservoir, inflatable cuff, and two pumps. (A) Squeezing pump on right transports fluid from reservoir into cuff, and (B) squeezing pump on left deflates cuff into "open" position. (C) Implantation with bulbs placed in labia of female or in scrotum of male.

cuff, whereas compression of the other bulb deflates the cuff. The valves serve three functions: they control the direction of flow, they allow a variation in the pressure that can be produced in the system, and they divert fluid back into the reservoir whenever preset maximum pressure in the cuff is exceeded.

In prior quality control studies the prosthetic sphincter, including all of its component parts, has been activated over 44,000 times; this is the equivalent of voiding six times per day, three hundred sixty-five days per year, for over twenty years. The implanted prosthesis would be anticipated to last for more than twenty years unless the material deteriorates because of time or contact with body fluids. The fluid contained inside the prosthesis is radiopaque contrast material which would be excreted should the device be punctured accidentally.

Surgical procedure

The reservoir was attached by nonabsorbable suture material to the leading edge of the posterior rectus sheath, anatomically "the arcuate line of Douglas" (Fig. 1C).

The inflatable cuff was placed around the bladder neck, superior to the prostate in the male. The cuff surrounded the urethra distal to the bladder neck in the female. Care was taken not to enter the urinary tract or the vagina in the female. In the male, precise identification of the bladder neck for safe dissection and placement of the cuff required that the bladder be open during this portion of the dissection.

The tubing ran to the cuff and from the reservoir through the inguinal canal. From the inguinal canal the tubing continued until it

reached the bulbs which were placed in subcutaneous pockets created in the labia of the female or in the scrotum of the male. Complete technical surgical details are not presented in this report since the surgical technique is expected to evolve.

Case Reports

Case 1

A forty-five-year-old totally incontinent woman gave the following past history. In June, 1970, she had excision of a urethral diverticulum and a suburethral plication for treatment of urgency as well as mild stress incontinence. She developed a urethrovaginal fistula after which she was dry only when the bladder was almost empty. The fistula was repaired vaginally in August, 1970, after which she had total incontinence even though the fistula was closed. Her incontinence was aggravated by coughing or straining, and at times she experienced urgency incontinence.

In January, 1971, she underwent abdominal urethropexy in the manner of Lapedes and a reduction urethroplasty of the distal urethra through a vaginal approach. She was cured of her incontinence for a period of three weeks, after which her symptoms recurred exactly as before. In March, 1971, the abdominal urethropexy was repeated and a reduction bladder-neck-plasty was performed, but her total incontinence continued exactly as before.

The patient could not tolerate the cystostomy tube placed at the time of the surgical procedure in March, 1971, nor could she tolerate an indwelling catheter regardless of parasympatholytic drugs. Therefore, she wore diapers for her total incontinence.

TABLE I. Pre- and postoperative micturitional flow rates (case 1)

| Micturitional Event | Volume | Postvoiding Residual | Maximum Pressure | Flow (cc./second) | |
|---------------------|---------|----------------------|------------------|-------------------|------|
| | | | | Peak | Mean |
| PREOPERATIVE | | | | | |
| Case 1 | | | | | |
| I | 166 cc. | 64 cc. | 20 mm. Hg | 7 | 6 |
| II | 204 cc. | 4 cc. | 22 mm. Hg | 9 | 8 |
| III | 202 cc. | 2 cc. | 18 mm. Hg | 12 | 10 |
| POSTOPERATIVE | | | | | |
| Case 1 | | | | | |
| I | 264 cc. | ... | ... | 18 | 7.3 |
| II | 384 cc. | ... | ... | 17.5 | 5.1 |
| III | 255 cc. | ... | ... | 16 | 8.5 |
| Case 2 | | | | | |
| I | 235 cc. | 60 cc. | ... | 9.5 | 4.1 |
| II | 104 cc. | 186 cc. | ... | 7.5 | 2.1 |
| III | 265 cc. | 35 cc. | ... | 13 | 2.4 |

Physical examination. Pelvic examination disclosed the fact that urine leaked continuously but gushed freely with abdominal straining or coughing.

Laboratory examination. Intravenous pyelography revealed normal upper urinary tracts. Cystometrogram revealed a capacity of 600 cc. which gave the patient a feeling of abdominal fullness, but she had no intrinsic bladder sensation and did not experience the urge to void. This latter observation was made repeatedly at the time of cystometry as well as at cystoscopy. Voiding cystography revealed an incompetent urethra. Electromyelography and sphincter electromyography revealed evidence of vesical and urethral denervation.¹²

Urodynamic studies. Urodynamic studies during three micturitional events revealed generally poor bladder contractions with relatively poor flow. Flow rates were significantly lower than normal. These findings were consistent with denervation of the bladder or "diabetic bladder atony" (Table I).

Cystoscopy. Cystoscopy revealed an incompetent urethra with pale fibrotic walls which did not coapt, even when the patient's bladder was empty.

Surgical procedure. On June 9, 1972, the first prosthetic urinary sphincter was implanted in this patient. Marked difficulty was encountered in dissecting into the prevesical space and around the urethra because of extensive fibrosis from the four previous operations. Also, because of fibrosis surrounding the urethra, the cuff prepared for this patient did not completely surround the urethra. Only the sutures completed a 2-cm. gap to encircle the urethra. In spite of

this, testing in the operating room proved the prosthesis to be effective in restoring continence.

Postoperative hospital course. The patient voided satisfactorily for twenty-four hours following the surgical procedure but then developed acute urinary retention which required catheter drainage for eight days. She remained afebrile until the fourth postoperative day, when she had a temperature of 100.6°F. and urine cultures revealed greater than 100,000 colonies per cc. of *Streptococcus faecalis*. She was treated with appropriate antibiotic therapy.

On the tenth postoperative day, fluorocystography was performed after her bladder was filled with 300 cc. of radiopaque media. With the prosthetic sphincter closed, there was absolute continence in the standing position in spite of straining and coughing (Fig. 2). She voided satisfactorily with the prosthetic sphincter open, although she had a postvoiding residual of 60 cc.

Squeezing the bulbs in the labia caused slight discomfort on the right but exquisite pain on the left side for about five days, after which the patient experienced no discomfort on squeezing either of the bulbs.

Postoperatively, her voiding flow rates were comparable to those prior to surgery (Table I).

Postoperative course after discharge. Postoperatively the patient remained completely dry and experienced no difficulty voiding. She was comfortable and experienced no pain on activation of the prosthetic sphincter, either at the bulbs or inside the bladder neck area. The cuff surrounding the urethra was palpable on vaginal examination, and there was no tenderness noted. The patient leaked urine at the time of pelvic examination if the sphincter was open.

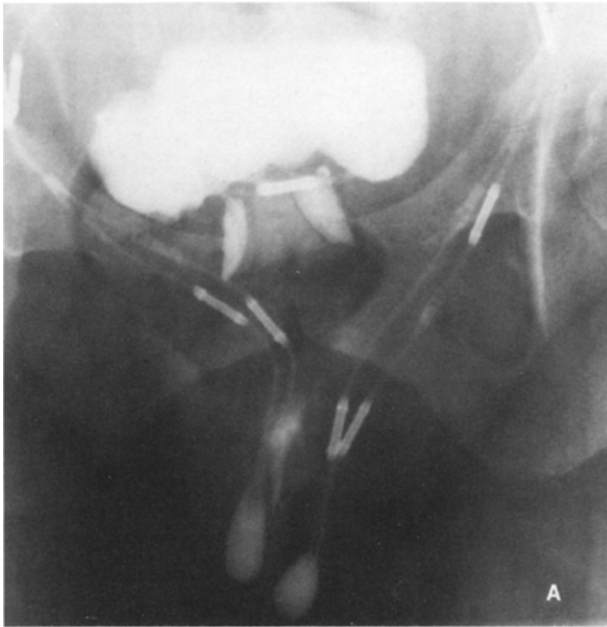


FIGURE 2. Case 1. Fluorocystography showing no leakage on coughing or straining while bladder contained 300 cc. radiopaque fluid, and (B) radiopaque fluid in prosthetic sphincter allows periodic radiographic evaluation.

However, there was no leakage when the sphincter is closed regardless of abdominal straining.

Three weeks after the operative procedure a routine urinalysis disclosed a urinary tract infection. She was treated with cephalexin monohydrate, which gave the patient a drug reaction manifested by nausea, vomiting, and fever. All of this subsided immediately when the ceph-

lexin monohydrate was discontinued. During the six-hour interval that the patient was vomiting and wrenching severely, she stated that she "did not leak one drop of urine." Two months following surgery she was free of urinary tract infection and completely asymptomatic without any urinary incontinence. Cystoscopy revealed normal bladder and urethral mucosa, and the urethra was observed to close concentrically on squeezing the bulb of the inflation pump.

Case 2

The second case was a thirty-six-year-old woman who had a myelomeningocele repaired soon after birth. Her entire life had been punctuated by recurrent episodes of urinary tract infections and urinary retention. She had been catheterized from time to time and found to carry postvoiding residuals of up to 1,300 cc. She was referred to us because of bilateral moderate hydronephrosis with the anticipation that an ileal loop diversion would be performed, but the patient was so obese that a collecting bag would not remain in place. Therefore, the patient was placed on a strict weight-reducing diet. After several months, the patient had not lost any weight, so an alternative plan was formed.

On December 10, 1971, she underwent a bladder flap urethroplasty to render her totally incontinent (Fig. 3).¹³ After this was accomplished, her hydronephrosis improved, and she was readmitted for implantation of a prosthetic urinary sphincter.

Physical examination. She had total incontinence such that a catheter was required to fill

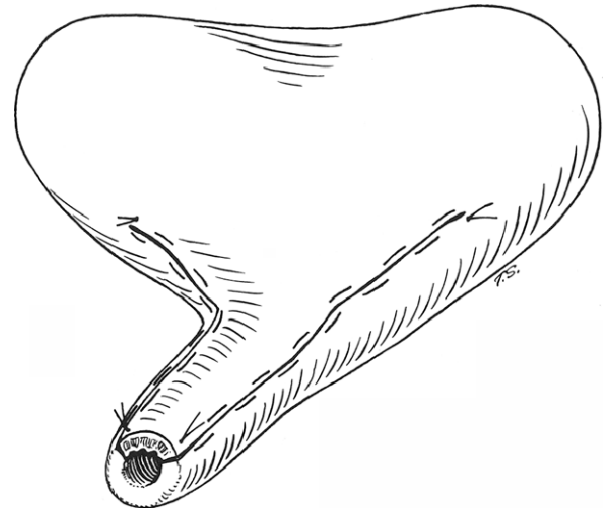


FIGURE 3. Advancement of anterior pedicle flap from bladder to urethral meatus enlarges caliber of urethra and causes total incontinence which improves emptying of bladder in patient with neurologic bladder dysfunction.

the bladder to test its continence. There was perineal anesthesia and a weak bulbocavernous reflex. The patient was ambulatory.

Laboratory examination. Complete blood count, blood urea nitrogen, creatinine, and fasting blood sugar test results were all normal. Urine culture revealed significant counts of *Escherichia coli*, *Proteus mirabilis*, and *Klebsiella*. Intravenous pyelography revealed normal upper urinary tracts without any caliectasis or ureteral dilation that had been present previously. Cystogram revealed an open bladder outlet with immediate loss of urine as the catheter was withdrawn. There were bladder trabeculations and multiple small diverticuli.

Cystoscopic findings. The urethra was quite patent. There were changes in the bladder typical of chronic cystitis, and the bladder was trabeculated, as demonstrated by cystography.

Urodynamic studies. Bladder pressures varied with straining and respiration, but there were no changes to indicate detrusor contractions. Flow was not recordable since there was continuous dribbling as fluid was instilled through a suprapubic percutaneous catheter into the bladder. There was no residual. Before the bladder flap urethroplasty to render her totally incontinent, she had had a peak urinary flow of 19 cc. per second, but with a postvoiding residual of 1,215 cc.

Surgical procedure. Implantation of the prosthetic sphincter was done on June 13, 1972, after antibiotic therapy had cleared her urinary infection. Surgery was quite difficult because of preexistent fibrosis. The posterior urethra was inadvertently lacerated, requiring vaginal incision and dissection for exposure and repair. A catheter was left indwelling for urethral healing. Again, the fibrosis surrounding the urethra was even greater than in the previous patient, and although larger sizes of prostheses were available, the largest size still left a 2-cm. gap. So, again, the sutures were tied so that only suture strands completed the encirclement. A patch of Dacron-reinforced silicone rubber sheeting was placed between the urethra and the sutures to prevent cutting into the tissues by the suture strands.

Postoperative hospital course. The hospital course was uneventful. The patient remained afebrile and healed without difficulty. On the ninth postoperative day, fluorocystography showed that she did not leak with 300 cc. of radiopaque media in the bladder, even though she strained and coughed while in a standing position (Fig. 3). On opening the prosthetic sphincter by squeezing the deflation bulb, the

fluid gushed out, and she emptied her bladder satisfactorily. Four hours after the voiding fluorocystogram, she was found to have urinary retention. This was relieved immediately with a gush of urine by squeezing the deflation bulb.

Postoperative urodynamic studies. Intraurethral-pressure studies easily located the prosthetic sphincter to be at the bladder neck. On inflation of the prosthetic sphincter, the intraurethral pressures rose and prevented the usual spikes in distal urethral pressure seen with coughing. Uroflowmetry revealed flow rates that were below normal but comparable to those seen after anterior urethropexy, Marshall-Marchetti-Krantz procedure, or urethral plication procedures (Table I).

Postoperative course after discharge. With 300 cc. in the bladder, it was impossible to obtain leakage with straining in a standing position, although on squeezing the deflation bulb there was an immediate gush of urine. A urinalysis revealed infection, and the patient has required continuous suppressive antibiotic therapy.

At a subsequent office visit seven weeks following the surgical procedure, the patient complained of having occasional leakage when the bladder became too full. Otherwise, she remained dry. Testing in the office, however, failed to disclose any leakage with the cuff fully inflated. Cystoscopy revealed an intact healed urethra and bladder, and closure of the urethra could be seen on activation of the prosthetic sphincter.

Case 3

A thirteen-year-old girl with paraplegia since twenty-one months of age, at which time she sustained an injury to her spinal cord secondary to an automobile accident, was the third case. Initially she was treated with Foley catheter drainage but subsequently had been managed with diapers for her urinary incontinence. She had had few urinary tract infections during the previous ten years. Her main complaint was urinary incontinence.

Physical examination. She had sensory and motor paraplegia to the seventh thoracic vertebra level. The patient had previously had alcohol rhizotomy for spasticity in the legs. The bulbocavernous reflex was weak but present. Eliciting the bulbocavernous reflex triggered reflex voiding but with incomplete emptying of the bladder. Manual examination revealed a fair amount of residual urine which could be expressed easily from the bladder by bimanual compression of the bladder.

Laboratory examination. Urinalysis revealed

bacteriuria without pyuria with culture revealing the presence of *Pseudomonas aerogenosa*.

Urodynamic studies. On cystometrogram, at a volume of 50 to 60 cc., the patient exhibited vesical hyperreflexia. Micturition studies showed pressures of voiding ranged from 70 to 80 mm. Hg with intermittency and marked detrusor-sphincter dyssynergia and incomplete emptying. Cineradiographic studies revealed a bladder diverticulum, a large residual, but no reflux. The upper urinary tracts were normal on intravenous pyelography. The proximal urethra was dilated so that when the bladder neck opened the proximal urethra opened even wider, whereas the distal one third of the urethra was narrow, as though it was constricted by the pelvic floor.

Surgical procedure. On July 25, 1972, a prosthetic sphincter was implanted around the distal one third of the urethra without difficulty.

Postoperative hospital course. Except for a slight temperature elevation during the first three days following surgical procedure, the patient's postoperative course was uneventful. She was discharged afebrile on the ninth postoperative day.

Postoperative fluorocystographic studies showed good retention of urine. She has been followed as an outpatient and given either bethanechol and/or parasympatholytic drugs to regulate the detrusor reflex.

Follow-up cystoscopy on August 10, 1972, sixteen days' postoperatively, revealed excellent tissue tolerance of the prosthesis. The urethral mucosa overlying the prosthesis was normal in appearance, and the urethra could be observed to shut concentrically while inflating the prosthetic sphincter.

Case 4

The fourth patient was an eighteen-year-old white male born with myelomeningocele, which was repaired shortly after birth. Urologically, the patient was well with normal upper urinary tracts and without the problem of urinary tract infections. The patient had been totally incontinent and had implantation of a Berry prosthesis for treatment of his incontinence in 1966, with no beneficial effect.

Physical examination. He was a healthy-appearing male whose physical examination results were normal except for saddle anesthesia and partial motor and sensory loss in the legs. He was ambulatory, although he walked with a wide gait. He wore diapers and pads for his incontinence.

Laboratory examination. Urinalysis showed

many white blood cells; however, urine culture was negative. Voiding cystogram showed a normal proximal urethra, and the bladder neck opened freely. The bladder emptied completely without reflux. Dye was seen in the urethra even before straining. Intravenous pyelography revealed normal upper urinary tracts.

Cystoscopic findings. Cystoscopy was not done on this patient in view of negative urine test results and normal radiographic studies.

Surgical procedure. Implantation of a prosthetic sphincter was done on July 26, 1972. To ascertain the exact location of the bladder neck and to facilitate safe dissection posteriorly between the bladder and the seminal vesicles, the bladder was opened. Once the prosthetic sphincter was in place the bladder neck was seen to open and close properly as the device was activated.

Postoperative hospital course. Postoperatively, a catheter was not left indwelling, and the patient was observed to void with a small dribbling stream throughout the first day. A residual urine of 520 cc. required the insertion of a retention catheter for five days. On July 31, 1972, his Foley catheter was removed after the bladder had been inflated with 200 cc. of dye and fluorocystography proved excellent control and good bladder emptying.

Voiding flow rates were satisfactory. He was dry on coughing, straining, walking, sitting, and has slept with dry bed clothing for the first time in his life. He was discharged on August 9, 1972.

Case 5

A twenty-four-year-old white woman who sustained a fracture of the spine in 1968 was the fifth case. Although she had paraplegia at first, she later had good use of her legs but has continued to have neurologic bladder dysfunction. She has been followed-up every six months with intravenous pyelograms. Cystography showed reflux into the left collecting system and periodic intravenous pyelography showed progressive dilation of her ureters. She strained to urinate. An ileal loop diversion had been recommended because of progressive hydronephrosis, reflux, and recurrent urinary tract infections.

Physical examination. Pelvic examination disclosed denervation of the perineum, since there was protrusion and relaxation of the perineal musculature. The anus protruded, and there was some descent of the uterus, particularly when the patient strained as she had to do to urinate. The bulbocavernous reflex was present but weak.

Laboratory examination. Urinalysis revealed 15 to 20 red blood cells per high-power field and many leukocytes.

Intravenous pyelogram showed normal upper urinary tracts. Fluorocystography showed reflux in the left kidney, and there were multiple small diverticuli and cellules in the bladder. There was good peristalsis of the left ureter. There was incomplete emptying of the bladder, and the patient was observed to urinate only by very forceful straining.

Cystoscopic findings. There were chronic inflammatory changes in the mucosa. The ureteral orifices were rather large in appearance, particularly on the left. Multiple cellules and diverticuli were seen.

Urodynamic studies. Cystometrogram showed a progressive increase in pressure from 10 to 40 cm. of water by the time she had 400 cc. in the bladder. At this point the patient had considerable discomfort and then strained to produce a pressure in excess of 100 cm. of water. Urinary flow rate showed a peak of 31 cc. per second, with a mean flow of 13.8 cc. per second, but she had 250 cc. residual. Repeat flow rate again showed 31 cc. per second with a mean flow, however, of 4 cc. per second and a residual of 80 cc.

Micturition study showed that this patient had to strain to generate a bladder pressure of 180 mm. Hg to produce urinary flow. At this pressure she produced a flow of only 12 cc. per second. After voiding 125 cc., she had a residual of 265 cc.

Surgical procedure. On July 27, 1972, the patient underwent left ureteral reimplantation to correct her reflux and a bladder flap urethroplasty to render her incontinent. Then, a prosthetic urinary sphincter was also implanted.

Postoperative hospital course. The patient had an afebrile, uneventful postoperative course. On August 4, 1972, the patient's bladder was filled with about 250 cc. of dye, and the prosthetic sphincter was noted to work properly, according to fluorocystography.

Results

Incontinence

Radiologic. The bladders of the five patients were filled with radiopaque media at the time that their catheters were removed. Then the patients were placed in a standing position and observed fluoroscopically. With the prosthetic sphincter in the closed, or inflated, position, none of the patients leaked even though they strained, coughed, or laughed.

Office examination. Each of the patients has been examined in the office and observed to be dry regardless of position, coughing, or straining. Once the prosthetic sphincter is opened, the three women leak spontaneously, the thirteen-year-old girl leaks with the Crede, and the eighteen-year-old man dribbles. All void freely with the prosthetic sphincter in the open position.

Clinical history. In cases 2, 3, and 5, patients notice occasional leakage when their bladders are full. Cases 1 and 4 show perfect results and cases 2, 3, and 5 excellent results.

Urodynamics

Postoperative voiding flow rates are as good or better than preoperative rates in all five patients. Case 5 shows significant improvement, since she can now produce an excellent stream without abdominal straining, whereas previously she had to strain forcefully to create an intravesical pressure of 180 mm. Hg before voiding could occur.

Tissue acceptance

All of the patients with normal sensory perception (case 3 is a complete paraplegic) noted some discomfort over the inflation and deflation pumps for three to ten days after surgery, but none has experienced any discomfort since discharge from the hospital. None has been aware of discomfort as the urethra is compressed by the prosthetic sphincter. Cases 1, 2, and 5 have reported no discomfort with sexual intercourse. No discomfort is noted on palpating the prosthetic sphincter rectally or vaginally. None of the prostheses has become infected. Cases 1 and 2 have both had cystitis postoperatively; the infection noted in case 1 has been cleared, but case 2 requires continuous suppressive antimicrobial therapy. The others have had no signs of urinary infection. Postoperative cystoscopic examinations have shown good healing with normal tissue acceptance in each case.

With the prosthetic sphincter in a closed position, each patient has been catheterized without difficulty. Therefore, should the patient develop urinary retention, catheterization is possible even though the prosthetic sphincter were to lock in a closed position.

Comment

Since this prosthetic urinary sphincter does not interfere with voiding while in the "open" position, it represents the first acceptable method of treating incontinence caused by neurologic disease. Unlike the electrical pelvic-floor stimulator, it does not depend on muscle for closure of

the urethra; therefore, it is applicable to patients with spina bifida who have no pelvic-floor musculature. The device can also be applied to treat women with stress incontinence with neuromuscular denervation secondary to previous urethral repair.

We consider this implantable prosthetic urinary sphincter to be the first of a series of electromechanical developments designed to render complete volitional urinary control to the patient with neurologic disease. Some patients may require only the prosthetic sphincter to accomplish this. Others will require a complete take over of the micturition reflexes. To accomplish this, an electronic volume sensor that will transmit a signal to the patient when the bladder is full will replace a sensory deficit. A radio-coupled electrical bladder stimulator, designed with no wires to connect electrodes and no current spread, will replace a detrusor-motor deficit.

Since the prosthesis does not come into contact with urine, there should be no problem with encrustations. Whereas the device partially depends on the cushioning effect of the body tissues for closure, it simulates the function of a true sphincter.

Although the number of cases presented is small and there has been only a short time for follow-up observation, the following points regarding its clinical application can be made:

1. The device does, indeed, render the patient completely continent. Since this is so in such desperate patients for whom there was no other method of treatment, further attempts to refine and develop this prosthesis are justified.

2. There has been excellent tissue acceptance. The bulbs located beneath the skin remain easily palpable, mobile, and without tenderness or apparent fibrosis. The cuff is palpable per vagina or rectum, and it, too, has remained palpable without apparent reaction in the surrounding area. There has been no evidence of fibrosis around the prosthesis to interfere with its action. These results, of course, were expected, since our prior experimental studies in animals had also proved good tissue acceptance without apparent fibrosis.¹⁴

Two of the patients in this series required other operative procedures incidental to or preceding the implantation of the prosthetic sphincter. One patient had ureteral reimplantation to correct reflux. While reimplantation to cure reflux is not usually done in a patient who must strain to void, there is no reason not to reimplant the ureter in a patient who is first made so totally incontinent that he can void by gravity flow. To

accomplish such free voiding and obviate the need for abdominal straining, two patients in this series underwent a new operative procedure designed especially for this.¹³ The bladder flap urethroplasty was done because of our observation that the usual bladder neck Y-V-plasty does not consistently render the patient with a neurologic bladder totally incontinent, even if the apex of the "V" flap is carried into the distal urethra. But in the two patients in this series a bladder flap, created first on the anterior surface of the bladder and then advanced throughout the entire length of the urethra, did, indeed, allow the patients to void by gravity flow, thus obviating the need for abdominal straining to unusually high bladder pressures to properly empty the bladder (Fig. 3).

Prior studies in animals showed a thin, pliable capsule to form around the prosthesis, but there was no fibrosis.¹⁴ Theoretically, however, excessive fibrosis around the prosthesis could impair the function of the device. Thus far, there has been no indication of this condition.

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