

Roberto Olianas, M. Fisch

Contents

18.1	Introduction	272
18.2	History of the Artificial Sphincter	272
18.3	Indications and Patient Selection	273
18.4	Pre- and Postoperative Patient Preparation	273
18.5	Surgical Technique	274
18.5.1	Placement of the Cuff	274
18.5.1.1	Bladder Neck Sphincter	274
18.5.2	Membranous Cuff	275
18.5.3	Distal Double Cuff	275
18.5.4	Transcorporal Cuff	275
18.5.5	Placement of the Balloon, Pump and Connection	275
18.6	Activation/Deactivation and Function	276
18.7	Results	276
18.8	Conclusion	277
	References	278

18.1 Introduction

Urinary incontinence is a disastrous disease with a severe impact on the social aspects of life. It occurs in all ages but mainly in elderly patients, with an incidence of 17%–55% in females and 11%–34% in males (Thom 2003). The type of incontinence depends on the underlying disease. Of the various causes of urinary incontinence, sphincteric incompetence is one of the most common.

In the male patient, in addition to genuine incontinence, surgical interventions often are responsible for the loss of urine. After radical prostatectomy, urinary incontinence is reported in 0.5%–87% (Hodges 2002; Rudy et al. 1984) of patients. Specialized centers with a high number of interventions report incontinence rates as low as 8%–9% (Walsh et al. 1994). Interestingly, the rates are much higher in nonselected patient groups. Bishoff reported an incontinence rate at 1 year after surgery of 47% after retropubic and of 30% after perineal prostatectomy (Bishoff et al. 1998); the patients were collected based on a cancer registry. Incontinence after transurethral resection of the prostate for benign disease is less common. Stress incontinence is reported to be 2.1%, total incontinence 1% (McConnell 1994). The incidence of stress incontinence following open prostatectomy is 1.9%, total incontinence 0.5% (McConnell 1994). After external beam radiotherapy for localized prostate cancer, an incontinence rate of 1.3% after 5 years was reported (Lee et al. 1996). Other causes for an incompetent sphincter in the male are congenital anomalies such as bladder exstrophy, traumatic rupture of the urethra or neurogenic disturbances.

In the female patient, the yearly incidence of urinary incontinence is approximately 0.6% over the age of 50 (Holtedahl and Hunskaar 1998). The major reason for stress incontinence is genuine. Numerous procedures are available to correct genuine stress incontinence in females, all of which emphasize repositioning of the urethra to allow adequate transmission of intra-abdominal pressures. However, there is a group with recurrent incontinence. Other reasons for an incompetent sphincter in females are, similar to males, congenital anomalies, trauma or neurogenic disturbances.

A number of procedures and devices have been developed for the treatment of total urinary incontinence, one that has been very successful is the artificial urinary sphincter developed by the American Medical Systems, Inc.

18.2 History of the Artificial Sphincter

In 1946, Foley developed a pneumatic artificial sphincter based on the principle of the Cunningham clamp (Foley 1947). An inflatable clamp was placed around the penile urethra connected with a device. In 1972 a new generation of artificial sphincters (AS-721) was introduced by Scott et al. (1973). It consisted of a cuff, a reservoir and two pumps – one for inflating, the other for deflating the device. A set of valves controlled the direction of flow within the system. The cuff was placed around the bladder neck (females, males) and the bulbous urethra (males). This system was used between 1972 and 1974. In the following years, several modifications were made, each model designated with a number (741, 742, 761, 791, 800) (Montague 1981; Scott 1989). One significant change was the use of a balloon rather than valves to control the pressure applied to the urethra, another the implementation of a dip-coated all-silicone rubber cuff instead of a Dacron-reinforced cuff (791 and 800) (Montague 1981; Scott 1989). The disadvantage of all these models was that the bladder neck/urethra was compressed by

the cuff immediately after surgery, increasing the risk for necrosis and erosions (Hald 1986). To avoid these complications, Furlow (1981) propagated a two-staged procedure: only 8–12 weeks after implantation of the device, the tube from the pressure balloon was connected and thereby the sphincter activated. The AS 800, introduced in September 1982 and still the current model, solved these problems (Scott 1985). It consists of an inflatable cuff, a pressure-regulating balloon, a pump and connecting tubes. Initially the cuff was made of Dacron-reinforced rubber; since March 1984 it has been made of specially dip-coated silicone rubber (Scott 1985). It contains a deactivation mechanism. A valve, refill-delay resistor and a deactivation button are incorporated in the pump. The inflatable cuff is available in different lengths.

18.3 Indications and Patient Selection

Urethral sphincter insufficiency with severe (stress) incontinence is the indication for sphincter implantation.

Incontinence should be measured objectively using a *pad test* and should be severe (more than five pads in 24 h) (Perez and Webster 1992). A preoperative *urodynamic investigation* is of utmost importance in order to evaluate the filling and storage phase of the bladder and to exclude detrusor hyperreflexia. A concomitant hyperactive detrusor (urge incontinence) has to be successfully treated prior to sphincter implantation. The maximum urethral closing pressure should be below 30 cm H₂O (Guralnick et al. 2002). Bladder capacity should be sufficient; otherwise bladder augmentation has to be considered. A *voiding cystogram* and a *cystoscopy* exclude infravesical obstruction. There should be no residual urine. In patients with neuropathic lesions, surgery is usually required to decrease outflow resistance and residual urine prior to sphincter implantation. If the patient is willing and able to perform intermittent catheterization, procedures reducing outflow resistance can be avoided.

The upper tract – investigated by *intravenous urography* and/or a *renal function study* should be normal.

Perfusion of the tissue underneath the cuff is important. Any alterations of the blood supply of this tissue such as those caused by irradiation, previous surgery and trauma will increase the risk for erosion. The patient should be mentally and manually able to handle the device.

18.4 Pre- and Postoperative Patient Preparation

Patient preparation is of importance to avoid early infections and should be standardized. The standard used at the AK Harburg follow below:

- Preoperative:
 - I. Urine culture should be sterile. Any infection has to be treated.
 - II. The day before surgery, the patient starts washing the lower abdomen and genital area with iodine or chlorhexidine solution.
 - III. Intravenous antibiotics are given 12 h prior to surgery. Antibiotics with a broad spectrum including Gram-negative bacteria and staphylococcus are preferred.
 - IV. Immediately before surgery, the skin is washed with povidone–iodine soap for 15 min. Final skin preparation uses an alcoholic Betadine solution.

- Postoperative:
 - I. The sphincter is deactivated.
 - II. A small (12F) catheter is inserted at the end of surgery after deactivation but removed within 48 h.
 - III. If a drainage had to be inserted it should be removed as soon as possible (best within 24 h).
 - IV. Antibiotic treatment is continued until the 5th postoperative day.

18.5 Surgical Technique

For all surgeries, the patient is in a lithotomy position with thighs nearly parallel to the floor so the legs can be moved upward and downward.

Shortly before implantation, all parts of the sphincter (cuff, balloon and pump) are flashed with the last filling solution used. The distal end of the tubes are clamp (bolstered peanut clamps) in order to avoid air bubbles.

18.5.1 Placement of the Cuff

18.5.1.1 Bladder Neck Sphincter

In the female, a vaginal pack is inserted to allow easier identification of the dissection layer for cuff placement. Access is gained to the retropubic space by a low Pfannenstiel incision. The bladder neck and endopelvic fascia are exposed. Palpation of the balloon of the transurethral catheter allows easy identification of the bladder neck. The tissue posterior to the balloon is grasped between the thumb and the index finger. If the patient has had no previous vaginal surgery, the plane between the bladder neck and vagina can be created with right-angled scissors. In case of previous surgery, opening the bladder is recommended. Palpation from below and above allows correct identification of the scarred plane and enables dissection without bladder or vaginal perforation. A right-angled clamp is used to pull the cuff sizer through the previously dissected tunnel. Having withdrawn the catheter, the cuff size is determined (normally 6–7 cm). The cuff is easily placed in position underneath the still present cuff sizer.

In males, a transverse lower abdominal incision (Cherney) is preferable to the Pfannenstiel incision as it allows a better exposure of the bladder neck and prostate. After dissection of the bladder neck, the endopelvic fascia is incised lateral to the prostate. Pulling the transurethrally inserted catheter, the exact position of the bladder neck is determined and dissected bluntly below the prostate using the thumb and the index finger. The remainder of Denonvilliers fascia is perforated using a right-angled clamp. The sizer is inserted after having enlarged the space, and the exact size of the cuff is determined. The cuff is positioned in the same manner as in females and closed.

18.5.2 Membranous Cuff

A midline perineal incision is made and the bulbocavernosus muscle and the crura of the corpora cavernosa are exposed. The central tendon of the perineal musculature is dissected and the urethra carefully exposed until the muscular layers of the pelvic diaphragm are seen. The diaphragm is split just underneath the bifurcation of the corpora and above the membranous urethra having contact with the pubic bone. Then the urethra is dissected from the pubic bone using a right-angled clamp. After determining the adequate length of the cuff, it is placed around the most proximal part of the urethra, covering the underlying bulbocavernosus muscle. After having sutured the bulbocavernosus muscle to the central tendon, the cuff is located in a position very close to the pelvic diaphragm. This location prevents leakage caused by the patient's sitting on the cuff.

18.5.3 Distal Double Cuff

A perineal midline incision is also made and the bulbocavernosus muscle exposed. Dissection is forwarded in the distal direction. The urethra should be dissected from the corporal bodies over a distance of about 4 cm. Two cuffs, each 4.5 cm in length, are placed around the urethra and closed. Both cuffs have to be positioned close to each other.

18.5.4 Transcorporal Cuff

A distal cuff location is often mandatory in patients after previous erosion or in those requiring revision because of urethral atrophy at the original cuff site. A distal dissection of the urethra increases the risk for urethral injury and erosion. Using a transcorporal dissection, the tunica albuginea is left on the dorsal wall of the urethra, allowing safer mobilization and increasing the size of the tissue being interposed. This technique was described by George D. Webster (Guralnick et al. 2002). The only modification of our technique is the tunica closure of the corpora. In Webster's original technique, the tunica was closed with sutures; in our modification we only cover the corpora defect with a fibrin sponge (Tacho-comb r). A contraindication for this cuff location is normal erectile function.

18.5.5 Placement of the Balloon, Pump and Connection

In patients with a bulbar positioned cuff, an additional small inguinal incision has to be made. The external fascia is incised, the underlying muscle layer split and the peritoneum exposed. Through a small incision, the *balloon* is positioned intraperitoneally. Some surgeons prefer an extraperitoneal paravesical position of the balloon. The dissected layers are closed. The tube leading out from the cuff is threaded subcutaneously from the perineal incision to the inguinal incision and placed over the external inguinal ring. In distal double-cuff patients, both tubes are brought up in the same way.

In patients with a bladder neck sphincter, the balloon is inserted inside the peritoneal cavity, which can be easily accessed by the same incision. Subsequently, the fascia is closed after having placed the cuff and the rectus muscle is readapted. The tubing from the cuff and balloon are brought out separately using a passing tool. The tubing should exit through the full layer of muscles to enter the subcutaneous area.

For implantation of the pump, a subcutaneous space in the inguinal area is dissected free from the underlying fascia. From this point, blunt dissection is carried out down to the scrotum of the male or the labium of the female. The pump should be placed immediately underneath the skin. A long nasal speculum is useful for dissecting an appropriate space and for introducing the pump. The pump is held in position using a Babcock clamp

The balloon is filled with an isotonic mixture of sterile water and radiopaque medium. The hysteresis curve of the pressure-regulating balloon indicates that fairly constant pressure is present with filling volumes of 18–22 ml. Therefore the complicated filling method described by the manufacturer of the AS 800 is not necessary and a simple filling with 22 ml will provide the same device pressure. For a double cuff, 24 ml are used. The tubes are shortened. Connection of the tubes is performed using quick connectors.

18.6 Activation/Deactivation and Function

■ **Deactivation.** The artificial sphincter is deactivated immediately after surgery. Therefore the deactivation button on the lateral side of the pump is squeezed. This moves a poppet valve into a locked position so that no fluid is transferred until activation. With the cuff in a bulbar position, the sphincter remains deactivated for 6 weeks. A bladder neck sphincter can be activated earlier when the patient is able to use the pump without pain. Deactivation can be done at any time and is mandatory (with the cuff empty) before any manipulation such as catheterization and urethrocystoscopy (at least in those patients with a bulbar position of the cuff).

■ **Activation.** Activation is achieved with a sharp squeeze on the pump, which releases the poppet.

■ **Function.** If the system is activated the filled cuff compresses the urethra. Squeezing the pump transfers fluid from the cuff into the balloon. The pressure-regulating balloon begins automatically re-pressurizing, but the resistor of the control assembly delays the refill for approximately 3–5 min and thereby allows bladder emptying.

18.7 Results

The success rate after sphincter implantation ranges between 85% and 95% with a revision rate of 25% over 5–6 years of follow-up.

These results can be achieved in men, women and children. In our opinion, surgery in children should be postponed until after 10 years of life. The defect rate of the artificial sphincter is about 7.6% (Elliot and Barrett 1998). The infection rate for the first implantation is 3%–4%, and for revisions it is higher (9%).

Tissue atrophy underneath the cuff to some degree is unavoidable. In our experience, it is the most common cause of early recurrent incontinence (6–12 months) in

Table 18.1. Review of the literature: women

Author	N	Median follow-up (years)	Success	Revisions
Diokno	32	2.5	91%	21%
Mundy	29	?	19%	2%
Webster	25	2.4	92%	0
Norlen	7	5.5	4%	1%
Buzelin ^a	96	2.5	82%	17%
Richard	89	4.2	88%	17%
Schreiter	164	8.7	91%	41%
Total	442		88.8%	24%

^a Buzelin: implanted and injected material, 1996.

Table 18.2. Review of the literature: men

Author	N	Success	Revisions
Barret (1997)	417	88.2%	23.1%
Thomas (1996)	28	86%	28%
Casale (2002)	142	86%	25%
Wilson (2002)	37	66%	
Spiess (2002)	30	83%	40%
Mulcahy (1996)	97	88%	(double cuff)
Schreiter (1999)	369	86%	29%

males (48/321 patients after RRP, 15% in our casuistic) and female patients (22/144 patients, 15.2% of patients).

Despite the introduction of the narrow-backed cuff in 1987, fluid loss due to cuff leakage remained the most frequent late (after more than 5 years) mechanical complication in males (32/321 patients after RRP, 10%) and females (19/144 patients, 13.2%).

Some of the results of the literature are summarized in Tables 18.1 and 18.2.

18.8 Conclusion

The artificial sphincter (AMS 800) is the only model available today. The results achieved are excellent if the indication is correct and perioperative management is careful and adequate. The ideal patient is one with genuine stress urinary incontinence and normal bladder function, although hyper- or hyporeflexia is not an absolute contraindication if treated before or after sphincter implantation. The surgical technique is relatively simple and the only challenge is the choice of the appropriate cuff and reservoir size. Complications include urethral atrophy, erosion, infection and bladder instability. The mechanical failures of the prosthesis have diminished with improved design and manufacturing. Patient satisfaction is high. Currently the only method to treat urinary incontinence in a physiological way is the implantation of the artificial urinary system (AMS 800).

References

- Bishoff J, Motley G, Optenberg S, Stein C, Moon K, Browning S, Sabanegh E, Foley P, Thompson I (1998) Incidence of fecal and urinary incontinence following radical perineal and retropubic prostatectomy in a national population. *J Urol* 160: 454–458
- Elliott DS, Barrett DM (1998) Mayo Clinic long-term analysis of the functional durability of the AMS 800 artificial urinary sphincter: a review of 323 cases. *J Urol* 159: 1206–1208
- Foley F (1947) An artificial urinary sphincter: a new device and operation for control of enuresis and urinary incontinence. *J Urol* 58: 250–259
- Furlow W (1981) Implantation of a new semiautomatic artificial genitourinary sphincter: experience with primary activation and deactivation in 47 patients. *J Urol* 126: 741–744
- Guralnick ML, Miller E, Toh KL, Webster GD (2002) Transcortical artificial urinary sphincter cuff placement in cases requiring revision for erosion and urethral atrophy. *J Urol* 167: 2075–2079
- Hald T (1986) Artificial urinary sphincter. *World J Urol* 4: 41–44
- Hodges CV (2002) Vesicourethral anastomosis after radical prostatectomy: experience with the Jewett modification. *J Urol* 118: 209–210
- Holtedahl K, Hunskaar S (1998) Prevalence, 1 year incidence and factors associated with urinary incontinence: a population-based study of women 50–74 years of age in primary care. *Maturitas* 28: 205–211
- Lee W, Schultheiss T, Hanlon A, Hanks G (1996) Urinary incontinence following external-beam radiotherapy for clinically localized prostate cancer. *Urology* 48: 95–99
- McConnell J (1994) Benign prostatic hyperplasia guideline panel. Direct treatment outcome – urinary incontinence. Benign prostatic hyperplasia, diagnosis and treatment, pp 105–106
- Montague D (1981) The Scott-Bradley-Timm artificial urinary sphincters. *J Urol* 125: 796–798
- Perez L, Webster G (1992) Successful outcome of artificial urinary sphincters in men with post-prostatectomy urinary incontinence despite adverse implantation features. *J Urol* 148: 1166–1170
- Rudy DC, Woodside JR, Crawford ED (1984) Urodynamic evaluation of incontinence in patients undergoing modified Campbell radical retropubic prostatectomy: a prospective study. *J Urol* 132: 708–712
- Scott F (1985) The use of the artificial sphincter in the treatment of urinary incontinence in the female. *Urol Clin Am* 12: 305–315
- Scott F (1989) The artificial urinary sphincter, experience in adults. *Urol Clin Am* 16: 105–117
- Scott F, Bradley W, Timm G (1973) Treatment of urinary incontinence by an implantable prosthetic sphincter. *Urology* 1: 252–259
- Thom D (2003) Variation in estimates of urinary incontinence prevalence in the community: effects of differences in definition, population characteristics and study type. *J Am Geriatr Soc* 46: 473–480
- Walsh PC, Partin AW, Epstein JI (1994) Cancer control and quality of life following anatomical radical retropubic prostatectomy: results at 10 years. *J Urol* 152: 1831–1836

Part VI

**Operative Therapy
of Fecal Incontinence**

VI