

## CHAPTER 19

### Committee 15

# Surgical Treatment of Urinary Incontinence in Men

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# Surgical Treatment of Urinary Incontinence in Men

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## I. INTRODUCTION AND SUMMARY

Surgery for male incontinence is an important aspect of treatment with the changing demographics of society and the continuing large numbers of men undergoing surgery for prostate cancer.

Basic evaluation of the patient is similar to other areas of incontinence and includes primarily a clinical approach with history, voiding record, and physical examination. Since most of the surgeries apply to patients with incontinence after other operation or trauma, radiographic imaging of the lower urinary tract, cystoscopy, and urodynamic studies may provide important information for the treating clinician.

Although prostatectomy for benign disease has become less frequent in many countries, the complication of incontinence is a rare but unfortunate occurrence that merits treatment. After a period of conservative therapy has been tried, surgical treatment, with implantation of the artificial urinary sphincter, has cured 75-80% of sufferers. Injection therapy with agents such as collagen has helped 40-50% of men in the short term and fewer in the long term.

Radical prostatectomy for prostate cancer, on the other hand, is performed far more frequently now than 10 years ago. Approximately 5-25% of patients will experience incontinence and of those a significant minority will require surgical treatment. The artificial sphincter has provided a satisfactory cure in most cases with a positive impact on quality of life. Sling procedures have also been reported to have a good outcome. Injectable agents have had a lower success rate and continue to be evaluated.

Incontinence following radiation therapy, cryosurge-

ry, other pelvic operations and trauma is a particularly challenging problem because of tissue damage outside the lower urinary tract. The artificial sphincter implant is the most widely used surgical procedure but complications may be more likely than in other areas and other surgical approaches may be necessary. Unresolved problems from the pediatric age group and patients with refractory incontinence from overactive bladders may demand a variety of complex reconstructive surgical procedures. Other unique problems encountered are fistulae between the urethra and skin and the prostate and rectum. Surgical reconstructions in experienced hands are usually successful.

With extensive worldwide use of the artificial sphincter in the surgical management of male incontinence, its complications and their management are well known. Durability of the device is an important aspect that impacts on outcome and cost of treatment.

Although the literature is replete with well done cohort studies, there is a continuing need for prospective randomized clinical trials.

## MATERIALS AND METHODS

The committee was charged with the responsibility of assessing and reviewing the outcomes of surgical therapy that have been published since the Second Consultation [1] for non-neurogenic male incontinence. Articles from peer-reviewed journals, abstracts from scientific meetings, and literature searches by hand and electronically formed the basis of this review. The outcomes were analyzed, discussed among the members of the committee and included in the chapter.

In order to rationally discuss surgical therapy the

incontinence problems were classified according to their etiology, i.e. either primarily sphincter or bladder related, and are listed in **Table 1**. Treatment of fistulae is covered separately.

Specific recommendations are made on the basis of published results and determined by the levels of evidence. Consensus of the committee determined the recommendations, which are found at the end of the chapter. A new surgical modality and recommendations for future research are also included.

**Table 1. Classification of surgically correctable problems**

**Sphincter related**

**POSTOPERATIVE**

- Post-prostatectomy for prostate cancer
- Post-prostatectomy for benign disease
- TURP and radiation for prostate cancer
- Post-cystectomy and neobladder for bladder cancer

**POST-TRAUMATIC**

- After prostatico-membranous urethral reconstruction
- Pelvic floor trauma
- Unresolved pediatric urologic incontinence
- Exstrophy and epispadias

**Bladder related**

- Refractory urge incontinence due to detrusor overactivity
- Small fibrotic bladder

**Fistulae**

- Prostatorectal (urethrorectal)
- Urethrocuteaneous

**II. EVALUATION PRIOR TO SURGICAL THERAPY**

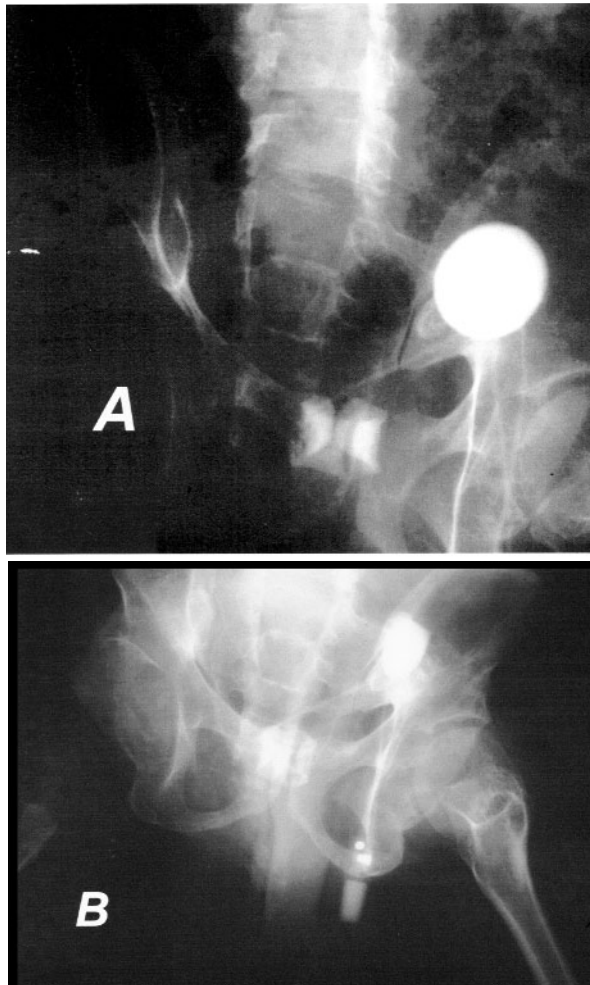
Before surgical treatment of the incontinent male is undertaken, the following evaluations should be done [2]. Basic evaluation includes history, physical examination (including neuro-urological examination: perineal sensation, anal tone, voluntary contraction and relaxation of the anal sphincter, bulbocavernosus reflex [3], urinalysis, and postvoid residual urine. A frequency-volume chart [4], or voiding diary (indicating daytime and nighttime frequency of micturition, incontinence episodes, voided volumes, 24-hour urinary output, etc.) is also helpful. No clear guidelines can be found in the literature indicating the minimum number of days necessary to furnish reliable data for a voiding diary. According to

Wyman et al. [5] the 7-day diary can be considered as the gold standard for voiding diaries. Recently Schick et al.[6] demonstrated that a 4 day frequency-volume chart is the shortest one which still gives reliable results, as compared to the 7 day diary. The pad test quantifies the severity of incontinence. The 24-hour home test is the most accurate pad test for quantification and diagnosis of urinary incontinence because it is the most reproducible.[7] The 1-hour pad test is widely used because it is more easily done and standardized. A pad test may be helpful in quantifying leak in AUS failures. Postvoid residual urine is a good estimation of voiding efficiency [8, 9]. These basic investigations should be done in every incontinent male when surgical therapy is planned.

Blood testing (BUN, creatinine, glucose) is recommended only if compromised renal function is suspected or if polyuria (in the absence of diuretics) is documented by the frequency-volume chart [10].

Further evaluation should be adapted to the particular patient. Cystourethroscopy is useful to verify integrity of the urethral wall (anterior aspect of the distal sphincteric mechanism in post-TURP incontinence [11], erosion by the cuff of the artificial sphincter, voluntary contraction of the pelvic floor, etc.) and the status of the bladder (trabeculation, stone, diverticula, etc).

Imaging techniques include plain film of the abdomen (KUB or Kidneys, Ureters, Bladder), in cases of incontinence following artificial sphincter implantation when during the original procedure the hydraulic system was filled with contrast medium. A KUB immediately following sphincter implantation serves as a reference point for subsequent comparisons [12]. **Figure 1** illustrates the case of a young spina bifida patient in whom an artificial sphincter has been implanted with the cuff around the bladder neck. After more than 10 years, he became suddenly incontinent. Second KUB compared to previous one clearly demonstrated fluid loss from the system. Contrast studies include cystography which may demonstrate an open bladder neck when bladder denervation is suspected [13] (e.g.: following abdomoperineal resection of the rectum). Cystourethrography may be used to demonstrate a fistula, stricture or urethral diverticulum, eg., following healing of the urethral wall erosion caused by the cuff of the artificial urinary sphincter (Fig. 2). Ultrasound is widely used not only to evaluate the upper urinary tract, but also to evaluate postvoid residual urine. The sensitivity of 66.7% and specificity of 96.5% when post-void residual is 100 ml or more is ade-



*Figure 1. Young spina bifida patient who had a bladder neck artificial sphincter implanted. After more than 10 years, he became incontinent. Early abdominal plain film, A, shows a full reservoir. After leakage started abdominal plain film, B, demonstrates loss of fluid from the reservoir.*

quate for routine clinical use[14]. It has been shown to be cost-effective when compared to catheterization [15]. Other modalities (transurethral ultrasound [16], magnetic resonance imaging of the external sphincter, etc.) are still under development.

### URODYNAMIC TESTING

**In the opinion of the Committee a thorough urodynamic evaluation to characterize the underlying physiopathology is important to perform prior to invasive therapy.**

However, there are factors that must be considered. In patients with incontinence secondary to radical prostatectomy who developed bladder neck stenosis, the urethral catheter can create obstruction giving false values for Valsalva leak point pressure. Sphincter weakness can be documented by the Valsalva [17]

or cough [18] abdominal leak point pressure, although not by urethral pressure profilometry. A recent study suggested that Valsalva leak point pressure is significantly lower than cough leak point pressure [19]. However, its reproducibility has been studied almost exclusively in women. Catheter size seems to have a significant influence, but the correlation is extremely high between the test-retest leak point pressure when the same size of catheter is used [20, 21].

In male patients, abdominal leak point pressure should be evaluated via a rectal catheter because urethral catheter is much more likely to invalidate Valsalva leak point pressure measurements than it does in female[22]. It has become evident that bladder volume influences Valsalva leak point pressure, i.e. it decreases with bladder filling [23-25]. This observation is not unanimous [26]. Unfortunately, no standardization of the technique and agreement upon it exist at the present time which somewhat limits its usefulness [27]. Measurement of leak point volume may also provide information on the functional capacity of the bladder [28]. Retrograde leak point pressure has been used to study incontinence following placement of an artificial sphincter [29, 30]. It correlates with the lowest abdominal leak point pressure[31]. The intraoperative use of this technique has been proposed and this allows early recognition of intraoperative urethral injury and mechanical malfunction [32]. Electrophysiologic studies, mainly sphincter electromyography, may be useful to document denervation of the pelvic floor when nerve injury or neuropathology is suspected [33]. Detrusor function is best evaluated by multichannel urodynamics. Its main purpose is to detect **detrusor overactivity and/or decreased compliance**. It can be coupled with fluoroscopic imaging, video-urodynamics. It has also been proposed by some to replace fluoroscopy with transrectal ultrasound [34, 35]. Ultrasound measurement of bladder wall thickness appeared to be a better predictor of bladder outlet obstruction such as an anastomotic stricture, than uroflowmetry [36].

Non-invasive pressure-flow urodynamic evaluation based on Doppler ultrasound seems to have potential for diagnosing bladder outlet obstruction [37]. However invasive, pressure-flow studies are still the gold standard in the incontinent male to rule out bladder outlet obstruction accompanied by detrusor overactivity [38]which in turn can cause incontinence.

The proposed evaluation of the incontinent male is summarized in **Table 2**.



**Table 2. Evaluation prior to surgical therapy**

- 
- History
  - Physical examination
  - Urinalysis
  - Urine culture
  - Post-void residual (by ultrasound)
  - Voiding diary (2-7 days)
    - polyuria without diuretics: BUN, Creatinine, Glucose
  - Pad-test
  - Cystourethroscopy
  - Urodynamics :
    - Multichannel urodynamics:
      - to characterize the incontinence and to detect detrusor overactivity, decreased compliance, and/or outflow obstruction
- 

### III. INCONTINENCE AFTER RADICAL PROSTATECTOMY FOR PROSTATE CANCER

#### 1. PREVALENCE

Urinary incontinence occurring after radical prostatectomy (RP) is still a significant problem. Although its rate has lessened [39] in these last few years primarily due to a better understanding of the pathophysiology and improvements in surgical technique, its prevalence has probably increased due to the dramatic increase of RP in developed countries which has led to overall increase in the number of patients affected. The reported rates vary according to incontinence definition as reported in **Table 3** [40-51]. Several recent series use definitions that include “total control”, “occasional leakage but no pad”, and “less than one pad”. In addition, the tools used to evaluate incontinence vary from validated questionnaires, interviews from a data manager, or response to the surgeon’s inquiry. Health related quality of life is strongly correlated with the level of incontinence and wearing one pad more significantly affects the quality of life than wearing no pad [52].

#### 2. RISK FACTORS

Reported risk factors for incontinence following radical prostatectomy include patient age at surgery, stage of disease, surgical technique, preoperative

continence status, prior radiation therapy, preoperative length of the membranous urethra and prior transurethral resection of the prostate (TURP). However, various studies have come to conflicting conclusions on specific risk factors. Risk factors for incontinence after TURP have not been as clearly defined, probably because the incidence is so low, making the accumulation of large prospective series of this type of incontinence difficult.

Advancing age as a risk factor is supported by several studies [53-58]. Steiner, et al found no correlation between age and continence status, but only 21 of the 593 patients were 70 years or older [59]. Others have found advancing age and number of co-morbidities to have a negative impact on recovering delay of continence during the first year post radical prostatectomy [60] but the rate at one or two years did not seem to be significantly affected [60].

Most large series have found no correlation between the stage of disease and incontinence rates [55, 56, 62, 63]. However, in certain cases, the stage of disease may affect the surgical technique (i.e. nerve sparing) and rates may be higher, but this appears to be a reflection on surgical technique and not disease stage [57]. Regarding surgical technique, the many parameters involved in continence may explain difficulties in understanding the benefit of certain technical points. The bladder neck preservation has been reported to improve continence at 3 months [63] but no difference was found at 6 and 12 months [64, 65]. Nerve sparing has no significant impact according to Steiner et al. [59] and Lepor and Kaci [42] recently confirmed this. Others did find benefit [66]. Recently, some authors have advocated laparoscopic and robotic radical prostatectomy. At this time the body of available data on continence is limited, but it would appear that continence rates are similar between open and laparoscopic/robotic approaches. Several studies have compared the techniques either retrospectively, [67] with meta-analysis [51] and found similar continence rates. One prospective, non-randomized study also showed similar rates of incontinence at 1 year [68]. Further prospective comparative studies with open surgery are needed. Perineal prostatectomy is done by only a limited number of urologists but is still advocated for obese patients and the continence rate was reported as similar to the retropubic route [69].

#### 3. PATHOPHYSIOLOGY

As in incontinence in general, post prostatectomy incontinence may be caused by bladder dysfunction,

**Table 3. Continence rates after radical prostatectomy according definition of continence, Definition 1: total control without any pad or leakage, Definition 2: no pad a day but few drop of urines, Definition 3: use no or one pad per day.**

*RRP: radical retropubic prostatectomy; RPP: radical perineal prostatectomy; LRP: Laparoscopic radical prostatectomy; Rx: radiotherapy*

Author	No. pts.	Mean age (years)	Continence follow-up at 12 months			Type of surgery
			def 1	def 2	def 3	
Kielb et al [40]	90	59.6	76%		99%	RRP
Sebesta, et al [41]	675	<65	43.7%	69.2%	82.2%	RRP
Lepor and Kaci [42]	92	58.7	44.6%		94.6%	RRP
Olsson, et al [43]	115	65.2	56.8%	78.4%	100%	LRP
Madalinska, et al [44]	107	62.6	33%	65%		RRP
Deliveliotis , et al [45]	149	66.5		92.6%		RPP
Harris, et al [46]	508	65.8		96%		RPP
Maffezzini, et al [47]	300	65.5		88.8%		RRP
Hofmann, et al [48]	83			74.7%	88%	RRP+/-Rx
Ruiz-Deya, et al [49]	200	63			93%	RPP
Augustin, et al [50]	368	63.3			87.5%	RRP
Rassweiler et al [51]	219	65			89.9%	RRP
	219	64			90.3%	LRP

sphincter dysfunction or a combination of both. Complimentary investigations are helpful to rule out bladder outlet obstruction or significant bladder dysfunction. In addition to incontinence symptoms, storage and voiding symptoms may be associated [69, 70]. Urodynamics demonstrated that the sphincter incompetence occurs as the sole cause in more than two thirds of patients, while isolated bladder dysfunction (detrusor overactivity, poor compliance, detrusor underactivity during voiding) is uncommon occurring in less than 10% [71, 72]. However, sphincter and bladder dysfunction can coexist in at least one third of incontinent patients. Bladder dysfunction may occur de novo after prostatectomy perhaps induced by bladder denervation; may be caused by outlet obstruction, or may be related to pre-existing factors such as the age. Impaired detrusor contractility and poor compliance resolved in the majority of patients within 8 months [73]. Decreased sphincter resistance may be due to tissue scarring in some cases and reflected by a low urethral compliance, however this parameter is difficult to measure [71]. This scarring may lead to an anastomotic stricture evidenced by endoscopy or urethrography, and is clinically suspected when both incontinence and decreased force of stream coexist.

The pre-operative length of the membranous urethra

determined on MRI has been shown to be related post-operative continence. When urethral length was greater than 12 mm, 89% of the patients were continent at one year versus 77% with or less than this length. Urodynamic studies revealed that a reduced functional urethral length was a predictive parameter of incontinence [66, 74, 75].

Different components of the urethra may be involved. The urethral intrinsic component responsible for passive continence as well as the extrinsic component responsible for active continence may be involved as demonstrated in a prospective urodynamic alpha blockade test [76].

This may explain paradoxical passive incontinence despite a high voluntary urethral pressure. Post-operative disruption of the innervation of the posterior urethra may also be involved and can affect both motor and sensory functions [77, 78]. In clinical practice, urodynamic evaluation of a urethral weakness may be assessed by resistance to antegrade leakage (ALPP or VLPP), retrograde leakage, or profilometric measurement (MUCP) [79]. However no such parameters have been correlated to outcomes of treatments for the correction of post prostatectomy incontinence.

The state of a patient's pelvic floor may also influen-

ce continence or return to continence after RP. Physiotherapy and pelvic floor rehabilitation have been shown to improve or enhance continence (decreased time to final continence level) in the post operative period in two randomized studies, if such measures are instituted before or immediately after catheter removal [80, 81].

Maximum difference between physiotherapy and no treatment is achieved at 3 months, with almost no difference at 12 months. Another study showed that providing patients with instructions for pelvic floor muscle exercise alone was equivalent to biofeedback or electrical stimulation [82]. A randomized study in which randomization occurred 6 weeks after surgery showed no difference in continence at 6 months [83]. On the same note studies in which physiotherapy was used as a treatment modality for established incontinence have shown more variable results [84-87].

#### 4. SURGICAL AND MINIMALLY INVASIVE TREATMENTS

##### a) Urethral bulking agents

Urethral bulking is a minimally invasive treatment proposed for post prostatectomy incontinence, and theoretically works by adding bulk and increasing coaptation at the level of the bladder neck and distal sphincter. It can be done in an office or outpatient setting in a retrograde or antegrade fashion. Several different agents have been used for urethral bulking in men including bovine collagen (Contigen), and silicone macroparticles (Macroplastique). All agents share the similar problems including the need for multiple injections, deterioration of effect over time, and very low cure rates.

For collagen, “success rates” for post-prostatectomy incontinence range from 36-69%, with 4-20% of patients reporting being dry [88-95]. Unfortunately, the end points in most of these studies are subjectively based, making comparisons difficult; however, it is clear that cure rates (total dryness) are low, and multiple injections are required to achieve modest rates of subjective improvement. There is no advantage of delivery technique (retrograde vs. antegrade). Several authors have identified factors which negatively affect results include extensive scarring or stricture formation, previous radiation, and high grade stress incontinence and low ALPP [89, 91, 92, 95]. One study reported more favourable results for collagen in treating incontinence after transurethral prostatectomy as opposed to radical prostatectomy

(35.2% ‘social continence’ versus 62.5%) [92]. It appears that collagen injection does not adversely affect outcomes of artificial sphincter implantation and does not increase the complication rate [96]. However, inconsistent or marginal benefits induce direct costs and residual pad costs, therefore a potential savings has to be considered if a majority of the patients finally treated with an artificial sphincter.

Other bulking agents such as polydimethylsiloxane (Macroplastique®) have shown some initial success, but results also deteriorate over time. Bugel and co-workers treated 15 patients. They noted rapid deterioration after initial improvements with success rates of 40%, 71%, 33%, and 26% at 1,3,6, and 12 months respectively [97]. They also noted that a urethral closure pressure of at least 30 cmH<sub>2</sub>O was essential for success.

Several other bulking agents are currently used or are under investigation for female stress urinary incontinence. Although there is minimal data on the use of these agents in men with post RP incontinence, it is certainly hoped that their effect will be better than currently available agents. These agents include carbon coated zirconium oxide beads (Durasphere®), hyaluronic acid and dextranomer (Zuidex®), dimethyl sulfoxide/ethylene vinyl alcohol copolymer (Uryx™), and hydroxylapatite spheres in carboxyl-methylcellulose carrier (Coapatite).

#### CONCLUSION

Bulking agents remain the most minimally invasive treatment for post RP incontinence after conservative measures. All agents for which there is peer-reviewed data available, show only modest success rates with very low cure rates. Effects tend to deteriorate over time. It remains to be seen if improvements in outcomes can be achieved with alternative agents, or if the concept of urethral bulking has achieved its maximal benefit with the agents available now. **(Level of evidence 3; Grade of recommendation C)**

##### b) Male sling

The male sling procedure utilizes the concept of passive external urethral compression, and has recently emerged as treatment for post prostatectomy incontinence. The male sling is actually based on the concept similar to that described by Kaufman and associates in the early 1970’s [98-100]. At that time a high rate of failure, septic complications and pelvic pain as well as the advent of the mechanical artificial



urinary sphincter (AUS) led to the abandonment of the Kaufman prosthesis. Now with the higher prevalence of post prostatectomy incontinence and patient wishes for less invasive surgery and a non-mechanical device the concept has been revisited. Procedures have been developed based on principles used to treat female stress urinary incontinence using biological and synthetic graft materials. These procedures rely on compression from the ventral side of the urethra rather than the circular compression caused by a natural or artificial sphincter.

Schaeffer and Stamey described the bulbourethral sling which uses Dacron bolsters placed under the urethra and suspended to the anterior rectus fascia by sutures [101]. Data on this procedure are limited to retrospective analyses from the two authors who described the procedure and it never gained widespread popularity. In the initial report from 2 centers, 64 patients were included and 56% were “dry” and 8% “improved” at a mean follow up of 22.4 months [101]. Almost one-third needed secondary retightening procedures and patients with radiation fared poorly. Subsequently, Clemens, et al reported a questionnaire-based study of 66 men from a single institution and 41% were cured and 51% improved but mean follow up was only 9.6 months [102]. They also reported that the bulbourethral sling did not cause significant outlet obstruction [103]. Others have described a bulbourethral sling using a polypropylene mesh graft with or without a porcine dermis backing to reduce the risk of erosion [104]. In two small studies of 9 [105] and 16 [104] patients cure rates range from 56-69% and failure rates from 22-25% at a mean follow up of 14 months. Recently, John described the bulbourethral composite suspension where porcine dermis is secured to the bulbospongiosus muscle and a 1 cm wide polypropylene sling is placed over this and passed through the retro-pubic space to emerge from two suprapubic incisions (similar to the tension free vaginal tape procedure in women) [104]. He reported a 69% cure and additional 6% improvement in 19 patients, with a mean follow up of 14 months. Eight intraoperative bladder perforations healed without complication.

More recently the bone anchored perineal sling has become popular. There have been several abstracts on the technique, but the peer reviewed literature is limited. In 2001, Madjar, et al reported on 14 patients with post RP incontinence that underwent the procedure with a synthetic or cadaveric fascial sling [106]. At a mean follow up of 12.2 months, 86% were “cured” wearing none or 1 pad. Comiter reported a

76% cure and 14% “substantially improved” rate in 21 men with post prostatectomy incontinence using polypropylene mesh with a mean follow up of 12 months [107]. A recent update, with a mean follow up of 25 months in 36 men, reported 67% were pad free and 14% used one pad/day [108]. Additionally, 80% of men reported from small to no bother (UCLA/RAND questionnaire) from incontinence after sling. Urodynamic follow up in 22 men, revealed that the sling had no significant effects on voiding function and no man was obstructed postoperatively [109]. Onur and colleagues reported on 46 men with a mean followup of 17 months (6-26) [110]. They used different materials for the sling (allograft dermis, allograft fascia lata, porcine small intestine submucosal (SIS) graft, synthetic mesh, and a composite of synthetic and dermis). Overall they reported 41% of patients dry and 35% improved (50% reduction in the number of pads). All patients in whom allograft or xenograft alone were used failed.

Additionally, patients with mild (1-2 pads) or moderate (3-5 pads) incontinence fared better than those with severe (> 5 pads) incontinence. In a followup study the same group reported on the use of the UCLA/RAND questionnaire to assess outcomes [111]. Seventy-two percent of patients stated that postoperative urinary leakage was a small to no problem: 59% were completely satisfied with the procedure while 11% were halfway satisfied.

## CONCLUSION

In the short term, in a limited number of small series, the male sling appears to perform reasonably well. However, interpretation of results must be guarded as definitions for cure or success vary greatly. In addition most studies include patients with less than one year follow up. Selection criteria for who are the best candidates have not yet been defined, but preliminary data reported in abstract form would suggest that patients with lower and moderate grades of incontinence will fare better.

Longer followup is obviously needed before definitive recommendations can be made. Nevertheless, in countries where the cost of an artificial urinary sphincter (AUS) is a critical issue or for patients demanding a less invasive procedure or non-mechanical device, a sling procedure could be an interesting alternative to artificial sphincter for minor or mild incontinence. **(Level of evidence 3; Grade of recommendation C)**

**c) Artificial urinary sphincter**

The artificial urinary sphincter remains the most effective long term surgical treatment for post RP incontinence due to sphincteric insufficiency. However, due to the cost of the device, patient reluctance to have or inability to use a mechanical implant, and fear of complications, it is not ideal for all patients. In addition the development of less invasive techniques (as described above) has given patients new options for treatment. Ultimately the choice of AUS will be based upon patient dexterity, economics, degree of incontinence and patient expectations from surgery.

The AUS has the longest track record of success in the treatment of PPI. Two studies have reported that about half of the patients with severe incontinence will undergo AUS implantation [112-113]. However, these studies were conducted before male slings are bulking agents became popular. The success rates for AUS as defined by a continence status of zero to one pad per day range from 59% to 87% [114, 115], as shown in **Table 4** [114, 116-123]. The lowest rates are from patient administered questionnaire. Pad free rates range from 10-72% [117, 124-128]. Nevertheless, high satisfaction rates 87% to 90% are consistently reported, even without total continence [118, 122, 124].

One potential downside of the AUS is the need for periodic revisions in a number of patients. Revision and explantation rates due to mechanical failure, urethral atrophy, infection and erosion vary considerably among studies with respectively reports of 10.8-44.6% and 7-17% [128]. Actuarial freedom from revision at 5 years is estimated at 50% [121].

The long term efficacy of the AUS was demonstrated

by Fulford et al who reported that at 10-15 year followup, [129] 75% of patients with an implanted AUS either still had or died with a functioning device. Revisions include replacement of the malfunctioning part, cuff replacement, repositioning or downsizing due to urethral atrophy, a second or tandem cuff [130, 131] or transcorporal cuff placement [132].

Transcorporal cuff placement, which involves inserting the cuff through the corporal bodies to avoid perforating the dorsal aspect of the urethra, can be particularly useful for patients with prior radiation or urethral erosion; however potency if present will be compromised. Some have advocated tandem cuffs not only as a salvage procedure, but also as a primary procedure for men with severe incontinence [133, 134]. An increased revision rate has been reported for patients who received pelvic radiation [117, 135] but was not found in a recent series [115].

The results for continence for radiated patients are variable with some studies showing lower success rates [114, 135] while others do not [127]. It has been recommended that such patients have a lower pressure reservoir and/or longer period of deactivation time [117].

**CONCLUSION:**

The AUS remains the gold standard for the treatment of PPI secondary to sphincteric insufficiency. Long term success rates and high patient satisfaction seem to outweigh the need for periodic revisions in some patients. Until similar experience is seen with newer, less invasive treatments, the AUS remains the reference standard to which all other treatments must be compared. **(Level of evidence 2; Grade of recommendation B)**

**Table 4. Results of the artificial urinary sphincter in post-radical prostatectomy incontinence.**

Author	No. pts.	Follow-up (yrs.)	0-1 pad/day
Montague [116]	66	3.2	75%
Perez and Webster [114]	49	3.7	85%
Martins and Boyd [117]	28	2	85%
Fleshner and Herschorn [118]	30	3	87%
Mottet, et al [119]	96	1	86%
Madjar, et al [120]	71	7.7	59%
Klijn, et al [121]	27	3	81%
Haab, et al [122]	36	7.2	80%
Goldwasser [123]	42	1.2	82%

## 5. TIMING OF SURGICAL INTERVENTION

There are no clear data on timing of a surgical intervention for the treatment of PPI, either with benign or malignant disease. Therefore, at present guidelines as to timing of the surgery cannot be formulated. A certain period of watchful waiting supplemented with conservative measures, particularly pelvic floor physiotherapy, seems to be a reasonable option.

Thus, conservative management may be tried for periods of up to 6-12 months depending on whether there is any progress noted by the patient. **(Level of evidence 4; Grade of recommendation C)**

## IV. INCONTINENCE AFTER PROSTATECTOMY FOR BENIGN DISEASE

### 1. INCIDENCE AND RISK FACTORS

The incidence of urinary incontinence after prostatectomy for benign disease has been reviewed and described in the AHCPR Benign Prostatic Hyperplasia Clinical Practice Guidelines [136]. The following percentages for stress incontinence and total incontinence, respectively, were reported:

- Open surgery (retropubic or transvesical prostatectomy): 1.9% and 0.5%.
- TUIP (transurethral incision of the prostate): 1.8% and 0.1%.
- TURP (transurethral resection of the prostate): 2.2% and 1.0%.

These figures were based on studies reported before 1990. Several other series were published after 1990. These series were reviewed for the 1st and 2nd International Consultations on Incontinence [1, 137]. A clear description of the method of follow-up and assessment of the continence status was indicated in only about one third of these studies. The incidence of incontinence after open surgery, TURP and TUIP was low but probably not as low as in the AHPCR review: The reported percentages ranged between 0 and 8.4%. Since the method of assessment of the continence status and the definition of incontinence is rarely stated it is actually not possible to make a distinction between simple stress incontinence and total incontinence. There is no clear indication that the incidence is affected by patient age or (resected) prostatic volume. [137]

In summary, the incidence of urinary incontinence after open surgery, transurethral resection of the prostate and transurethral incision of the prostate is low, but probably not as low as reported in the AHPCR review, which reported rates below 2%.

## 2. TIMING OF SURGICAL INTERVENTION

There are no clear data on timing of a surgical intervention for the treatment of incontinence, as mentioned above in the section on post-radical prostatectomy. Therefore, at present guidelines as to timing of the surgery cannot be formulated. A certain period of watchful waiting supplemented with conservative measures, particularly pelvic floor physiotherapy, seems to be a reasonable option. Thus, conservative management may be tried for periods of up to 6-12 months depending on whether there is any progress noted by the patient. **(Level of evidence 4; Grade of recommendation C)**

## 3. SURGICAL TREATMENT OPTIONS

### a) artificial sphincter

The literature on this subject was reviewed for the 1st and 2nd International Consultation on Incontinence [1, 137]. Candidates for treatment with the artificial urinary sphincter (AUS) are patients with incontinence due to intrinsic sphincter deficiency that have normal bladder compliance [138]. Detrusor overactivity is not an absolute contraindication but the response to medical treatment should be assessed before implantation of an AUS. The AUS has been placed around the bulbar urethra via a perineal route and around the bladder neck [139].

The above mentioned review of the results obtained with the AUS indicated that more than 70% of the men treated with the AUS for this indication are dry or almost dry after a follow-up of more than 2-3 years. However, most series on the AUS lump together post-prostatectomy incontinence after treatment for benign and malignant disease [137].

In summary, the AUS is a successful surgical treatment option for post-prostatectomy incontinence. It is the treatment of choice in patients with incontinence after prostatectomy for benign disease. **(Level of evidence 2; Grade of recommendation B)**

### b) Injectable agents

Most series lump together post-prostatectomy incontinence after treatment for benign and malignant disease. For collagen, "success rates" for post-prostatectomy incontinence range from 36-69%, with 4-

20% of patients reporting being dry. [88-95] As mentioned above, other bulking agents such as polydimethylsiloxane PDMS (Macroplastique®) have shown some initial success, but results also deteriorate over time. Bugel and co-workers treated 15 patients. They noted rapid deterioration of on initial improvements with success rates of 40%, 71%, 33%, and 26% at 1,3,6, and 12 months respectively [97].

Bulking therapy fails in up to 75% of men. Of those who are improved only a minority actually becomes dry with short-term follow-up. Therefore, bulking is of limited value in these men. **(Level of evidence 3; Grade of recommendation C)**

### c) Male sling procedures

Since Frangenheim described his first successful urethral sling suspension for post-traumatic stress urinary incontinence in 1914, various sling materials and surgical methods have been reported [140]. Rectus fascia, as described by Frangenheim, has distinct advantages over alloplastic materials with respect to erosion and infection risks. Homologous off-the-shelf-materials like lyophilized fascia lata have a higher infection risk, whereas the use of alloplastic materials like polypropylene mesh or polytetrafluoroethylene slings are associated with a higher incidence of urethral erosion [141]. According to various published techniques, the sling can be placed either underneath the bladder neck, the urethral bulb or the membranous portion of the urethra. The principle of

continence support is similar for all sling procedures and comprises passive compression of the urethra, which is dependent on the applied sling tension [142]. This mode of action favours sling procedures as a treatment option for intrinsic sphincter deficiency. However, the sling tension needed for restoration of continence cannot be standardized in any way, and therefore the success of the procedure probably depends heavily to the surgeon's experience. Overcorrection with consequent urinary retention and undercorrection with persistent recurrent incontinence are separated only by a narrow margin, which ensures continence, adequate bladder emptying, and patient satisfaction. Published success rates are shown in **Table 5** [101, 104, 105, 109, 142-144]. A new innovation, the readjustable sling procedure (REEMEX), has recently been introduced and its durability needs to be proved. [144]

## V. SURGERY FOR INCONTINENCE IN ELDERLY MEN

With an increase in the aging population and improvements in anesthesia, availability of less invasive and shorter surgical procedures, reduced blood loss and infection risk more aged patients are candidates for surgical treatment. Every surgeon should be aware of special risks in elderly patients which might require special perioperative care.

**Table 5. Results of sling procedures in males with stress urinary incontinence.**

Authors	No. Patients	Mean Follow-up (months)	Sling type	Cured (%)	Improved (%)	Failed(%)
Thüroff [142]	22	10.3	Fascia sling with suprapubic and perineal approaches	63.6	9	27.3
Ullrich & Comiter [109]	36	25	Perineal (Invance®)	67	25	8
John [104]	16	14	Polypropylene suspended suprapubically plus porcine skin collagen around urethra	69	6	25
Migliari et al. [105]	9	14	Polypropylene needle suspension	55.6	22.2	22.2
Cespedes & Jacoby [143]	9	13	Perineal (Invance®)	66.7	11.1	22.2
Schaeffer et al. [101]	64	18	Vascular graft bolsters with needle suspension	56	8	36
Sousa-Escandon et al. [144]	6	18	Readjustable synthetic suprapubic and perineal	83.3	16.7	-



A comprehensive literature search in geriatric urology was performed to examine age related outcome for surgical treatment of benign prostatic obstruction (BPO) and prostate cancer and surgery for incontinence including the artificial sphincter, sling procedures, injection of urethral bulking agents and intravesical botulinum toxin and resiniferatoxin. The search was conducted on the National Library of Medicine's PubMed database. The period covered was from 1985 to June 1st, 2004. Several guidelines and consensus reviews on surgical management of BPH and urinary incontinence such as a review on geriatric urology literature, published in 2003 by the American Society of Geriatrics [145] were included.

Data available are sparse, so the search did not differentiate between fit and frail elderly. Since the latter are defined as patients with continuous severe impairment and/or comorbidity they are usually not candidates for surgical treatment.

Conflicting data are reported on age as an independent risk factor for incontinence after radical prostatectomy. In most reports the patient's age and preoperative urine leakage are predictive of postoperative urinary incontinence, whereas some come to the opposite conclusion. [146] Advancing age as a risk factor is supported by a number of studies. [53-58] Steiner, et al [59] found no correlation between age and continence status, but only 21 of the 593 patients were 70 years or older.

Others have found that advancing age and number of co-morbidities have a negative impact on the speed of recovery of continence during the first year post radical prostatectomy [39, 60], but the rate at one or two years does not seem to be significantly affected [42].

Two of the most frequently used options for incontinence in men after prostatectomy are injection therapy with bulking agents such as collagen and the placement of an artificial urinary sphincter. Although the artificial sphincter is the current 'gold standard' for the surgical treatment for incontinence after radical prostatectomy [147], one could argue that therapy with bulking agents are better suited for older patients since the procedure is less invasive. Age however should not be the main reason to choose a

procedure which has been proven to be much less effective especially in patients who have moderate and severe stress incontinence after radical prostatectomy. Before implanting an artificial sphincter in a fit aged patient, mental status and dexterity have to be evaluated and discussed with the patient. No data could be found on how aging patients are able to manually operate and remember to use the artificial sphincter.

Most studies looking at these options for incontinence after treatment of localized prostate cancer did not look at age as an independent factor associated with certain complications [93, 96, 115, 148, 149]. Some investigators came to the conclusion that age does not predict treatment efficacy of bulking agents. [94, 150] (**Level of evidence 3**)

Recent series of slings with <2-year follow-up have shown satisfactory improvement rates, with results similar to those of the artificial urethral sphincter, although patient selection may be different. However, no stratification for age is available from the data.

## 1. TREATMENT OF DETRUSOR OVERACTIVITY

Therapy with intravesical neuromodulatory drugs such as capsaicin and resiniferatoxin as well as injection therapy with botulinum toxin has been extended to the treatment of nonneurological overactivity of the bladder after other treatment failed. These options are discussed in the section on Refractory Overactive Bladder (see below). No data were found on how these techniques work in aging bladders. Since detrusor contractility decreases with age [151] the incidence of bladder emptying problems might be expected to be higher in the elderly.

## 2. CONCLUSIONS

Age by itself should not preclude any patients from treatment. Although bulking agents are less invasive they have not yet been shown to be very effective. If co-morbidity, mental status and dexterity of the patient permit an invasive approach the implantation of an artificial sphincter, or a sling, should be offered to the patient. (**Level of evidence 3; Grade of recommendation C**)



## VI. INCONTINENCE AFTER EXTERNAL BEAM RADIOTHERAPY ALONE AND IN COMBINATION WITH SURGERY FOR PROSTATE CANCER

The risk of incontinence after external beam radiotherapy (EBRT) for prostate cancer is low at 0-11%. Lawton et al. [152] reported a risk of urinary complications of 7.7% in more than 100 patients, proportional to dose. Perez et al.[153] found incontinence in only 5 of 738 patients. Shipley et al. [154] reviewed more than 2500 cases with an incontinence rate of 0.5%. Similar incidences have been reported in more recent series. Madalinska et al. [44] reported an incidence of 6-7%. With three-dimensional conformal radiotherapy, Weil and colleagues [155] reported no incontinence in 168 consecutive patients and Hanlon et al.[156] , in a series of 195 men, found that post treatment urinary symptoms were no different from a control group without cancer. With conformal radiotherapy, Sandhu et al. [157] reported a 9% incidence of stress incontinence in 110 patients. In recent series the impact of EBRT followed by prostatic boost, for a total of 66-70 Gy, was evaluated. Scalliet and co-workers[158] reported urinary incontinence in 16% of 230 patients, however, Fransson and colleagues [159] reported an increase in urinary incontinence on a patient-administered symptom bother scale 3 years after treatment in 153 men compared to pretreatment status. The increase was from a mean of 0 at the start to 2 out of 10 at 3 years.

Pre-radiotherapy transurethral prostatectomy appears to be a risk factor for incontinence. Jonler et

al.[160] reported an incontinence rate of 11% with pretreatment TURP. Green et al .[161] and Lee et al.[162] also reported a higher risk of incontinence with pretreatment TURP with 5.4% and 2% respectively. There are no series reported on the treatment of patients who only have incontinence after EBRT.

Adjuvant radiotherapy is frequently given after radical prostatectomy and may not increase the rate of incontinence, although little data have been published. Petrovich et al. [163] reported no difference in incontinence in 2 cohorts of patients, one with and one without adjuvant radiation.

Furthermore, in a follow-up study the same group reported no late toxicity. [164] On the other hand salvage radical prostatectomy following external beam radiotherapy has been generally reported to have a high incidence of urinary incontinence [165, 166] possibly because of radiation induced fibrosis of the external sphincter. [166]

### SURGICAL TREATMENT

Results of surgical treatment of incontinence in this setting are based on retrospective clinical series. The most commonly published treatment modality is the artificial urinary sphincter as therapy for sphincter damage. The series published contain both patients who had and had not received radiotherapy. Collagen injections have also been reported in retrospectively analysed case series.

There has been a higher reported revision rate for the artificial sphincter following radiotherapy (**Table 6** 114, 115, 117, 126, 135, 167, 168) compared to low risk patients, 38% versus 22%. Although a recent report disputed the higher rate [115]. However, gene-

*Table 6. The artificial sphincter for incontinence after radiotherapy*

Study	Number of patients	Revision rate after radiotherapy	Continenence
Martins and Boyd [117]	34/81	38% for whole group	88%
Wang and Hadley [167]	16	25% (Infection and Erosion - 12.5%)	87%
Perez and Webster [114]	11/75	55%	63%
Gundian et al. [168]	15/56	22%	90%
Elliott and Barrett [126]	46/313	22%	-
Manunta et al. [135]	15/72	53% (Infection and Erosion – 20%)	73%
Gomha and Boone [115]	28/86	25% (Similar to a non- Radiated control group)	64%

rally this is due to a higher incidence of erosion and infection as well as urethral atrophy, possibly secondary to radiation induced vasculitic fibrosis of the urethra. [117] Good results are reported, however, and it is generally recommended that the cuff be inserted outside the radiated field. [169]

Collagen injection has also been reported for incontinence after radical prostatectomy and adjuvant radiation [90, 94, 170-173] or after salvage radical prostatectomy following radiotherapy [107,174] Continence results are poor compared to those without radiation. Very few patients have been reported on with the use of Macroplastique following radical prostatectomy and adjuvant radiotherapy.

The male sling has been reported in patients following adjuvant RT. In Comiter's group with the perineal compression sling 3/21 had radiation with no adverse sequelae. [107] However Schaeffer et al. reported that prior irradiation was the only identified factor that predisposed to failure. Their success rate following a single sling procedure was only 29% (2 of 7) for irradiated patients, and the corresponding rate for nonirradiated patients was 68% (39 of 57) [101] They postulated that the sling acts by compressing and elevating the urethra, thereby increasing urethral resistance to abdominal pressures. Theoretically, radiation-induced fibrosis of the urethral and periurethral tissues would make compression and elevation more difficult by reducing tissue compliance and mobility.

In summary, despite the frequently reported higher incidence of complications of the artificial sphincter in post-prostatectomy patients after adjuvant radiation, it has provided acceptable treatment benefits. Collagen injections have yielded poor results. Although the data are limited a perineal compression device may also be acceptable but suprapubic suspension bulbourethral slings may be less efficacious. **(Level of evidence 3; Grade of recommendation D)**

## VII. INCONTINENCE AFTER OTHER TREATMENT FOR PROSTATE CANCER

### 1. BRACHYTHERAPY

Brachytherapy is a form of radiation therapy in which radioactive materials are placed directly into the prostate gland. The incidence of incontinence following this modality is in **Table 7** [175-185] and

generally appears to be related to the treatment of post-brachytherapy retention. In a systematic review of brachytherapy series Crook et al. [184] reported the incidence of retention to be 1-14%. Many patients require prolonged or permanent alpha blocker or TURP. The main risk factor for incontinence after brachytherapy is TURP. Hu and Wallner [181] reported on the incidence of urinary incontinence after TURP/TUIP following prostate brachytherapy for prostate cancer. Of the 10 patients who underwent the outlet relaxing procedures for refractory urinary obstruction, 7 developed some degree of permanent urinary incontinence. They surmised that the cause may be multifactorial and may include physical damage to the urinary sphincters and the radiation dose to the urethral region. Surgical therapy has included the artificial sphincter, when required. [182] High dose brachytherapy that is administered over a short period of time may have reduced toxicity. [186] Urethrorectal fistula is another complication that has been reported in 1.8% of patients in a large U.S. medicare retrospective review. [182]

### 2. CRYOSURGICAL ABLATION OF THE PROSTATE

Cryosurgical ablation of the prostate is used for clinically localized prostate cancer as primary treatment or after unsuccessful external beam radiation therapy. The frequencies of the main lower urinary tract complications are listed in **Table 8** [187-198]. The artificial sphincter has been mentioned as one of the treatments for incontinence. [198] Cryotherapy is an adverse factor for collagen injections. Urethrorectal fistulae can also occur in up to 5% of treated patients. Severe incontinence and fistulae that occasionally results may have to be treated with extirpative surgery and diversion. [199]

### 3. INCONTINENCE AFTER NEOBLADDER CONSTRUCTION

The incidence of continence after neobladder construction following radical cystectomy for bladder cancer ranges from 85 to 100% during the day and 55 to 100% at night (**Table 9**) [200-211]. Most patients achieve daytime continence after one year and nighttime continence after 2 years.

Most of the published reports do not comment on specific surgical management and imipramine is mentioned as treatment only occasionally. Martins and Boyd [117] reported on 8 patients treated with the AUS for persistent sphincter weakness incontinence. Six of these underwent revisions, 3 for infec-

**Table 7. Incontinence after brachytherapy for prostate cancer**

<b>Author</b>	<b>% Incontinence</b>	<b>% Post TURP</b>	<b>% No TURP</b>
Beyer et al. [175]	1	-	-
Blasko et al. [176]	6	17	0
Stock et al. [177]	0	-	-
Wallner et al. [178]	0	-	-
Kaye et al. [179]	4	11	1
Blasko et al. [180]	13	0	
Hu and Wallner [181]	6	70	-
Benoit et al. [182]	6.6	-	-
Merrick et al. [183]	0	-	-
Crook et al. [184]	5.6	13	-
Talcott et al. [185]	45	83	39

\* Implant plus external beam radiation

**Table 8. Lower urinary tract complications after cryosurgery for prostate cancer**

<b>Author</b>	<b>N</b>	<b>% Incontinent</b>	<b>% Bladder outlet obstruction</b>
Shinohara et al. [187]	102	15	23
Bahn et al. [188]	210	3	9
Cox and Crawford [189]	63	27	29
Wieder et al. [190]	83	2.5	13
Cohen et al. [191]	239	4	2.2
Coogan and McKiel [192]	95	3.5	6
Sosa et al. [193]	1467	11	6.8
Long et al. [194]	145	83/2.0*	17.2
Pisters et al. [195]	150	60	43
Derakhshani et al. [196]	48	10.4	22.9
Long et al. [197]	975	7.5	13
De la Taille et al. [198]	43	9	4

\*Previously radiated/not previously radiated

*Table 9. Continence after neobladder construction for bladder cancer*

Author	Number of patients	Follow-up (mo)	Continence (%)	
			Day	Night
Alcini et al. [200]	34	12	100	83
Cancrini et al. [201]	89	24	97 (22% with SUI)	83
Elmajian et al. [202]	266	24	85	85
Studer et al. [203]	100	24	92	80
Benson et al. [204]	32	25	94	74
Abol-Enein and Ghoneim [205]	60	24	90	80
Rogers and Scardino [206]	20	24	90	55
Hautmann et al. [207]	211	36	85	85
Hautmann et al. [208]	363	57	95	95
Steven and Poulsen [209]	166	32.4	100 (After 5 years)	100
Abol-Enein and Ghoneim [210]	353	38	93.3	80
Carrion et al. [211]	56 ileum	41	91	68
	57 colon	41	86	68

tion and/or erosion and 3 for inadequate cuff compression. They cautioned against the use of the AUS and suggested alternatives such as intermittent catheterization at night. However, O'Connor and colleagues [212] reported a successful outcome, after AUS, with no complications in 5/5 men with incontinence after neobladder, with a mean follow-up of 22 months. Collagen has only been reported in women following neobladder construction. [213]

In summary there are not enough data upon which to recommend definitive surgical therapy, although the artificial sphincter looks promising. **(Level of evidence 3; Grade of recommendation C-D)**

## VIII. TRAUMATIC INJURIES OF THE URETHRA AND PELVIC FLOOR

Incontinence following posterior urethral injuries occurs in 0-20% of patients [214, 215] and is thought to be due to the extent of injury rather than to the method of management.

The data on surgical treatment are all retrospective

case series and the most commonly published surgical therapy is the AUS. The series published contain both patients with and without traumatic injuries. Perez and Webster [114] reported on 27 patients after urethral or bladder neck strictures. The revision rate was 41% and the continence rate was 85%. In Montague's [116] series 22 out of 166 patients had incontinence after trauma. He did not separate the results of this group from those of the other patients. Martins and Boyd [117] reported on only one patient out of 81 with a traumatic urethral injury. This patient was dry and required no revisions. Venn et al. [169] reported on 2 with pelvic trauma out of a total of 70. **(Level of evidence 2; Grade of recommendation B)**

Bladder neck reconstruction by excising the scar and narrowing the calibre was reported by Iselin and Webster [216] in 6 patients who had incontinence with an open bladder neck on cystourethrography, following urethroplasty for traumatic strictures. Bladder neck closure with a Mitrofanoff catheterizable abdominal stoma has also been reported as treatment following severe urethral or bladder trauma. [217] **(Level of evidence 3; Grade of recommendation C)**

For patients with severe bladder neck strictures and incontinence after radical prostatectomy Meulen et al. [218] and Elliot and Boone [219] reported on the use of a Urolume stent with a bulbar artificial sphincter. **(Level of evidence 3; Grade of recommendation C)**

In summary, while other treatments are possible the AUS provides a reasonable outcome in appropriate cases.

## IX. CONTINUING PEDIATRIC PROBLEMS INTO ADULTHOOD: THE EXSTROPHY-EPISPADIAS COMPLEX

Achieving continence and protecting the upper urinary tract are important goals of reconstruction in patients with exstrophy-epispadias complex. However, these tasks remain a formidable challenge for pediatric urologists. Urinary incontinence [220, 221] and other voiding problems [222, 223] due to these congenital anatomical abnormalities are continuing problems into adulthood. Although quite a few publications on the exstrophy-epispadias complex have appeared in the literature over the past 3 years, the long-term follow-up data into adulthood are still lacking [220], and there have been no significant changes in the management of urinary incontinence. Besides, definition of continence differs between studies. Despite the devastating nature of this disease, there has been no study addressing quality of life issue and psychological assessment in patients with exstrophy-epispadias complex. All the published materials consist of retrospective reviews of experience at various centers. Even major institutions are struggling to gather large series of patients. **Thus, we are still left with mostly level 4 and at most level 3 evidence.**

The management of the exstrophy-epispadias complex includes 2 principal aspects; initial management (primary treatment) and subsequent management of persisting incontinence. These 2 aspects are discussed separately. Based on the evaluation of the literature, recommendations are made at the last part.

### 1. INITIAL MANAGEMENT OF THE EXSTROPHY-EPISPADIAS COMPLEX

#### *a) Staged repair versus one-stage primary repair*

Staged surgical management of the exstrophy-epispadias complex (early closure with or without pelvic

osteotomy, repair of epispadias and bladder neck reconstruction) has been the standard approach [221, 224-228] although the staged approach has undergone significant changes since first advocated by Jeffs et al. [224] Success rates for staged functional closure are high with continence rates reaching 75% to 90% [224-226]. However, these results were based on highly select groups of patients and others failed to achieve such results. Continence rates of only 10% to 30% were reported with the staged approach [229, 230]. Complete primary repair described by Grady and Mitchell combined primary bladder closure with epispadias repair in one stage in neonates [231]. The idea was to optimize the chance for early bladder cycling and potentiate bladder development. It may also obviate the need for multistage repair of bladder exstrophy including bladder neck reconstruction. Although acceptable short-term results were achieved, the procedure has been criticized in view of 50% incidence of antireflux surgery needed for breakthrough urinary tract infections. A recent report from another institute has also shown that complete repair of exstrophy is feasible in neonates and older children after failed initial closure with acceptable morbidity [232]. Ureteral reflux was noted in 63% of renal units but did not require surgery in this series. There is short-term evidence of favorable outcome in newborns compared with older children [232]. However, we have to wait for long-term results from medical centers using this one-stage technique to know whether it is consistent in producing urinary continence and satisfactory sexual function.

The Mainz group has recommended primary urinary diversion (ureterosigmoidostomy, sigmoid rectal pouch, ileocecal pouch) with closure of the abdominal wall [233, 234]. The posterior urethra is closed as a seminal receptacle. While this approach is hardly used in North America, long-term reports have demonstrated excellent continence and upper tract preservation [233, 234]. Low pressure rectal reservoirs in children with bladder exstrophy have also provided excellent long-term outcome in continence (100%) and upper tract (97%) [235]. However, prophylactic alkalization does not prevent the long-term metabolic consequences. Subclinical metabolic acidosis and decreased linear growth are to be anticipated in more than 50% of patients, and moreover, significant bone demineralization is to be expected in all of these patients [235]. Thus, it is concluded that low pressure rectal reservoirs should be reserved for failed surgical reconstruction or patients presenting beyond the age suitable for reconstruction [235].



### ***b) Bladder neck reconstruction***

In a staged repair, bladder neck reconstruction is usually performed at age 4 to 5 years when the bladder gains enough capacity to provide for safe filling with good compliance and the child is ready to be dry and participate in a postoperative voiding program [224, 225]. The classic Young-Dees-Leadbetter technique has been modified in several ways [225, 228, 236]. The success of bladder neck reconstruction in both continence and emptying is highly dependent on the delicate balance between the bladder and outlet. Bladder capacity, contractility and outlet resistance are determinants of continence after bladder neck reconstruction [223]. A report from the Johns Hopkins group [225] describes that 77% of patients are completely dry day and night and voiding through the urethra without need for bladder augmentation or clean intermittent catheterization, and that another 14% have social continence (dry more than 3 hours during the day but still wet at night). Analysis of bladder capacity measurements under anesthesia prior to bladder neck reconstruction revealed that patients with a bladder capacity greater than 85 cc had a better outcome [225]. However, subjective success with continence and emptying does not necessarily correlate with objective findings [223]. Despite near or total subjective continence (dry intervals of at least 2 to 3 hours) and “good voiding” in 18 patients, there were clinical (recurrent urinary tract infections, epididymitis and bladder stone) and urodynamic voiding problems in 72%, including flow rate less than 10 ml/sec in 70%, post-void residual more than 33% of capacity in 50% and acute urinary retention in 17% [223]. Another report from the Toronto group also highlights the extreme difficulty in achieving volitional voiding in an unselected exstrophy population. Of 43 patients only 3 (7%) were voiding spontaneously through the native reconstructed urethra [237]. Thus, perseverance in the pursuit of volitional voiding is more likely to result in repeatedly failed bladder neck reconstruction and delay in the age at which continence is finally attained. Earlier recognition of the need for other storage procedures such as bladder augmentation and/or appendicovesicostomy and bladder neck closure may facilitate the timing of achieving continence and self-esteem, and achieve a satisfactory result with fewer operative procedures [237].

### ***c) Urodynamic evaluation***

There are several reports on urodynamic evaluation in patients who underwent bladder neck reconstruction [238-240]. The majority of closed exstrophy bladders have normal filling dynamics before blad-

der neck reconstruction [239]. However, bladder abnormalities are very common after bladder neck reconstruction, with about 50% incidence of poor compliance and detrusor overactivity [238-240]. Detailed urodynamic investigation in patients with bladder exstrophy, after the first operation to create a functional bladder, is vital to guide the next step of management and to compare objectively the surgical outcome of reconstruction using different approaches.

### ***d) The fate of the upper urinary tract***

Preservation of the upper urinary tract is the most important goal in any form of lower urinary tract reconstruction. In several series of exstrophy patients, significant upper tract deterioration was noted in 22% to 26% of patients [221, 241, 242]. Because any type of outlet procedure that elevates the outlet resistance can be a potential cause of upper tract deterioration, upper and lower tracts should be monitored by ultrasound to measure the efficacy of bladder emptying and to look for subtle upper tract changes even in patients with a good bladder storage function who are undergoing any kind of outlet procedure.

## **2. MANAGEMENT OF PERSISTING INCONTINENCE**

Regarding the management of persisting incontinence, there still remain considerable differences of opinion [233-235, 237, 242-247]. Various options are shown in **Table 10**. When planning the management of persisting incontinence, possible causes of incontinence should be thoroughly evaluated. Bladder and outlet storage function should be examined by detailed urodynamic investigation that allows individualization of treatment to optimize the chance of a successful outcome [240].

### ***a) Augmentation cystoplasty***

The late 1980s and early 1990s witnessed the more liberal use of bladder augmentation coupled with the option of catheterizable appendicovesicostomy (Mitrofanoff procedure). Overall rate of bladder augmentation in patients with exstrophy-epispadias complex has been 22% to 40% [221, 223]. Preservation of the native bladder template has been emphasized by The Johns Hopkins group and others [226, 248]. This has two advantages whether in the younger or older patients. First, using the template may decrease the amount of bowel needed for reconstruction. Second, if ureteral reimplantation is required, the bladder template is a better substrate for reimplantation than a subtaenial tunnel of the bowel [226].

**Table 10. Options for management of persisting incontinence after failed exstrophy-epispadias surgery**

---

**Revision of bladder neck reconstruction**

**Augmentation cystoplasty**

- Stomach
  - Ileum
  - Colon
- 

**Continent stoma (appendicovesicostomy)**

- with augmentation
  - with bladder neck closure
- 

**Urinary diversion**

- continent reservoir
    - colonic reservoir
    - ileocecal reservoir
    - rectal reservoir
    - gastrointestinal composite reservoir
  - conduit
- 

**Other outlet procedures**

- Kropp, Pippi Salle
  - Artificial urinary sphincter
  - Transurethral injections
- 

Stomach, ileum or colon can be used for bladder augmentation. Each type of augmentation has disadvantages that are inherent to the use of gastrointestinal segments, including metabolic derangement, urolithiasis [249], decreased linear growth [250], and hematuria-dysuria syndrome (in the case of stomach) [251]. A recent paper concludes that ileocystoplasty is safe and does not impact negatively on the linear growth or bone densities of patients with bladder exstrophy [252]. Gastrointestinal composite reservoir may be considered to offset the limitations of gastric and intestinal segments [243].

**b) Continent stoma**

There are many surgical procedures other than bladder neck reconstruction to increase bladder outlet resistance, including injection of bulking agents and placement of bladder neck slings and artificial urinary sphincter [247]. Unfortunately, these outlet procedures have variable degrees of success with none being successful in all patients. It is not uncommon for some patients to undergo multiple procedures in an attempt to achieve continence. When these attempts fail, the creation of a catheterizable continent stoma with or without bladder neck closure is the preferred procedure to achieve continence [253]. Continence rate of 100% was achieved by bladder neck closure compared with continence rates of 56% by bladder neck reconstruction only and 67% by

bladder neck reconstruction with augmentation and/or appendicovesicostomy [237]. However, success of bladder neck closure is dependent in part upon patients' compliance with intermittent catheterization [247]. In addition, those who have undergone bladder neck closure are at an increased risk for bladder stones [247].

**c) Urinary diversion**

Regardless of the type of continent urinary diversion used, most series demonstrate excellent success rates around 95% [253]. Based on the excellent continence rates achieved by urinary diversion compared with those by staged or one-stage primary repair, the Mainz group has recommended that all, but especially those who have failed previous treatment, are best served by conversion to a rectal reservoir or ileocecal pouch with catheterizable stoma [233, 234]. However, taking into account the long-term negative impact of rectal reservoir on metabolic milieu and bone density [235] and a high risk of neoplasia in those who have been exposed to mixing of urine and faeces in a colorectal reservoir [254], urinary diversion should be reserved as a last resort after failed surgical reconstruction.

**d) Outlet procedures**

If the initial bladder neck reconstruction (original or modified Young-Dees-Leadbetter in many cases) fails and a low outlet resistance is the only cause of persisting incontinence, another outlet procedure is worth attempting. Option includes Kropp or Pippi Salle bladder neck reconstruction, injection of bulking agents, placement of bladder neck slings and artificial urinary sphincter [247]. The presence of scarred tissue due to a previous surgery at the bladder neck may compromise the outcome. The value of the artificial urinary sphincter in dynamic control of outlet resistance in exstrophy patients is also questioned [221]. Vascularized gracilis muscle sling to wrap around the compromised bladder neck of incontinent patients has been reported as salvage surgery [245].

**RECOMMENDATION**

The published studies to date are retrospective case series with levels of evidence at best 3 with a grade of recommendation of C. The Committee has the following recommendations regarding the evaluation and treatment of persisting incontinence in adulthood.

- Patients with exstrophy-epispadias complex should be evaluated and managed in specialized centers
- A universal definition of continence should be established
- Persisting incontinence should be evaluated with urodynamics and its treatment should be individualized based on urodynamic findings
- Life-long follow-up is mandatory in terms of continence, voiding efficiency, upper tract status and other urological complications
- Comparative studies, including quality of life and psychological assessment, should be undertaken if possible.

## X. DETRUSOR OVERACTIVITY AND REDUCED BLADDER CAPACITY

### 1. REFRACTORY URGENCY INCONTINENCE AND IDIOPATHIC DETRUSOR OVERACTIVITY

According to the recent **Terminology of the International Continence Society** the overactive bladder syndrome refers to the symptoms of urgency, with or without urge incontinence, usually with frequency and nocturia [255]. *Detrusor overactivity* has also been redefined to indicate the urodynamic observation characterized by involuntary detrusor contractions during the filling phase that may be spontaneous or provoked. *Idiopathic Detrusor Overactivity* exists when there is no defined cause. This term replaces “detrusor instability”. *Neurogenic Detrusor Overactivity* is seen when there is a relevant neurological condition and replaces the term “detrusor hyperreflexia”. Although the old terms will be eventually be replaced they are still in common usage. The criterion for considering detrusor overactivity as idiopathic is questioned, as recently Ahlberg et al found that 82% of patients initially considered idiopathic on careful searching actually had pathology potentially leading to the problem [256].

Idiopathic detrusor overactivity is a normal situation early in life. Children have urgency incontinence as a stage in acquiring bladder control. The incidence of detrusor overactivity during mid-life years (20 to 60) has been estimated as 10% [257]. In the asymptomatic elderly, detrusor overactivity once again becomes

common, occurring in 50% of men over 70 [258]. In the symptomatic elderly, over 75 years old, it can reach 90% in men [259]. Detrusor overactivity may be a cause of severe storage symptoms such as frequency, nocturia, urgency and urgency incontinence. Conservative treatment of these symptoms such as bladder training and pharmacotherapy is discussed in other sections.

The use of intravesical neuromodulatory drugs such as capsaicin and resiniferatoxin was extended to detrusor overactivity of nonneurologic origin after the suggestion that its etiology involved the enhancement of the C fiber mediated spinal micturition reflex [260] and emerged as a minimally invasive procedure, with preliminary results shown in **Table 11** [261-265]. (**Level of evidence 3 – 4; Grade of recommendation C**)

For symptoms that are refractory, three interventional treatments have been reported: botulinum-A toxin detrusor injections, neuromodulation, and bladder augmentation.

#### a) *Botulinum-A toxin injection in bladder*

The minimal invasiveness makes this method very attractive but long term results in idiopathic detrusor overactivity are lacking (**Table 12**) [266-271]. The effects of its use are still not fully recognized, with possible systemic consequences [272] – generalized muscle weakness in two patients treated for neurogenic bladder overactivity and development of resistance to the drug [273, 274]. Most of the initial results come from its use in neurogenic bladders [275-278], with favorable results.

Data are lacking on dose, concentration, site(s), numbers of injections and long-term efficacy and side effects.. The studies with botulinum toxin detrusor injection are unclear about results and contradictory on the presence of residual urine and the need for intermittent catheterization. The reports do not discriminate gender precisely and two out of three mix neurogenic with idiopathic etiologies. (**Level of evidence 3; Grade of recommendation D**)

#### b) *Electrical stimulation and neuromodulation*

Electrical stimulation of the genital area was first used to control incontinence due to detrusor overactivity on an empirical basis [279], for different etiologies. Later, it was suggested that reflex sphincteric contraction induced by electrical stimulation can promote an inhibitory effect on detrusor activity, thus suppressing detrusor overactivity [280]. Many studies on external electrical stimulation for bladder

**Table 11. Intravesical capsaicin and resiniferatoxin for detrusor overactivity (males and females)**

Author	No.	Improvement	Duration of effect	Drug and dose	Side effects
Cruz et al. 1997 [261]	3 idiopathic (total of 16, including 3 males)	71% continence (overall total of 14) and 21% improvement	Up to 18 months	<b>Capsaicin</b> 125 ml of 30% alcohol in saline containing 1mM	Intense burning sensation
Kuo, 2003 [262]	13 idiopathic detrusor overact (41 total )	5 ( 38,5%)	2 to 9 months	<b>RTX</b> 10 ml of 100 nM RTX in 10% ethanol for 40 min	
	18 previous TURP	11 ( 61,1%)	Average 5 months		
Palma et al, 2004 [263]	25 females with idiopathic urge-incontinence	10 (40%) disappearance of urge-incontinence	1 month evaluation only	50 nM <b>RTX</b>	No mention of retention
Rios et al, 2004 [264]	60 females	Improvement equal to Ethanol 10% saline solution	1 month first evaluation	50nM <b>RTX</b> or 10% ethanol saline	solution Randomized double-blind placebo controlled
Silva et al, 2002 [265]	13 idiopathic (2 men 11 women) (12 incont)	11 improved (91%) in incontinence 3 (25%) dry	3 months follow up	100 ml 50nM <b>RTX</b> solution 10% ethanol in saline for 30 min	No retention or other problems

**Table 12. Botulinum-A Toxin detrusor injection**

Author	No.	Type of patients	Dose	No. punctures	Results	Comments
Harper et al, 2003 [266]	39 (13 men and 26 women)	Neurogenic and idiopathic origin (not described separately)	200 idiopath 300 neurog	20 to 30 sparing the trigone Flex. cysto.	Increase max bladder volume 174 to 589 ml	
Loch et al, 2003 [267]	30	Neurogenic and idiopathic	200 U	20 injections sparing the trigone	Significant improvement in 67% of the patients -> residual urge	No description of gender or whether neurogenic
Radziszewski et al, 2002 [268]	12 (6 female and 6 male)	Only idiopathic	Up to 300 U	10-15 injections sparing the trigone	1 months follow up 100% success no residual	Short follow up Inexact criterion of success
Rapp et al, 2004 [269]	35 (29 females and 6 males)	6 neurogenic	300 U	30 injections including trigone	34% resolution 26% improvement	40% failure
Kuo, 2004 [270]	30 (12 females and 18 males)	12 neurogenic	200 U	40 injections sparing the trigone	26% resolution 46% improvement	26% failure
Chancellor et al, 2003 [271]	10 (2 males and 8 females)	Only idiopathic	100-300 U	20-30 injections only in bladder base and trigone	80% improvement	Control group - 11 neurogenic with 73% improvement



inhibition on idiopathic urgency incontinence have been published, mainly in female patients [281-288]. The results vary from 45 % to 85 % success, with a mean of 38 %, and 26% improved. Electrodes implanted in the pelvic floor, did not yield good results [286].

Neuromodulation of sacral nerves has been reported as alternative therapy for incontinence, urinary retention and chronic pelvic pain. Good results have been published in treating neurogenic bladder dysfunction [289, 290]. Its use in refractory idiopathic urgency incontinence has been limited to few patients, mostly women. Bosch and Groen [291] presented results of chronic implantation in 15 women and 3 men, with an average age of 46 years.

Significant improvements in voiding frequency, average voided volume, number of incontinence episodes and number of pads used were found, with no deterioration in response to stimulation with time. However, with subsequent experience in 14 men only 2 patients had a partial response and the rest ultimately failed [292].

Shaker and Hassouna [293] implanted 18 patients with refractory urinary urgency incontinence, but only 2 were in men. Other studies are not clear about the etiology of the detrusor overactivity as neurogenic and non neurogenic causes are grouped together [293]. Yet, some reports focused on technical or specific aspects of the procedure and the same patients may be included in different publications [294, 295]. **Table 13** [296-303] shows some recent studies.

**Some reports are literature reviews [304] or technical modifications [305]. There are some articles with level or evidence 1 [296, 297] and 2 [292, 299], [300], with a grade of recommendation of B. However, due primarily to the cost of the device, relatively few men in the clinical trials, and poor results in one of the prospective trials, its general applicability to men with urgency incontinence is probably limited.**

### *c) Surgical treatment by bladder myectomy and augmentation*

Previously used treatments of surgical bladder denervation, open bladder transection, cystolysis, endoscopic phenol injections, hydrostatic bladder distention did not produce good results.

Bladder autoaugmentation or myectomy has been reported as an alternative to augmentation in neurogenic and non-neurogenic dysfunction. **Table 14**

[306, 307] shows recent results of this treatment in patients with non-neurogenic detrusor overactivity. Additional and longer term experience is still required to properly assess this modality.

Enterocystoplasty results are in **Table 15** [307-313], which includes male and female patients. Good results vary from 58% to 88%, with an average of 77%. A minimum of 10% of patients require intermittent catheterization for bladder emptying.

Ileum was the most frequently used bowel segment followed by sigmoid colon, although no scientific reason for use of any particular segment was given. The surgery, as reported in other sections, has a significant complication rate and should be considered carefully when applying it to these patients.

## **2. REDUCED BLADDER CAPACITY**

Fibrosis of the wall produces a low-volume low-compliant bladder, leading to diminished functional capacity. Symptoms of frequency and nocturia occur with progressive decrease in volume, but urinary incontinence may also be the consequence of a very small capacity, especially if accompanied by urethral weakness. The diagnosis can be suggested by the micturition chart, and confirmed by cystogram and or urodynamics.

The causes can be congenital or acquired. Acquired causes include multiple surgeries, inflammatory processes (chronic cystitis, interstitial cystitis, tuberculosis, schistosomiasis, chemical cystitis) or post radiation.

Bilharzial contracted bladder is a problem that is primarily limited to endemic areas in Africa and the Middle East. *Schistosoma haematobium* migrates to the veins of the vesical and pelvic plexuses, where the female begins to lay eggs, promoting an initial inflammatory response.

As a result, granulomatous lesions form in the lamina propria. Mucosal reactions vary from hyperplasia to polypoid cystitis. A contracted bladder occurs in 2 % of cases [314]. Bladder augmentation seems to offer reasonable results in these cases.

Similarly small fibrotic bladders of other etiologies can be treated successfully with enterocystoplasty. The results of this surgery are presented in **Table 16** [315-338].

These results are similar in all etiologies except for radiation. The poorer results after radiation may be



**Table 13. Neuromodulation for treatment of refractory urge incontinence due to detrusor overactivity (males and females)**

Authors	N	Success (dry)	Improved	Control group	Study and comments
Schmidt et al. [296]	34	47%	29%	42	prospective randomized
Weil et al. [297]	21	56%	19%	23	prospective randomized
Bosch et al. [298]	34 (females) 6 (males)	38% 16%	21% 16%		prospective longitudinal
Siegel et al [299]	41	46%	19%		prospective cohort
Grunewald et al [300]	18	39%	33%		prospective
Aboseif et al [301]	43 (5 males)	77%			not clear about etiology
Hedlund et al [302]	13	61,5%			2 men included, both dry
Roupret et al [303]	6 (all female)	17%	67%		

**Table 14. Detrusor myectomy for treatment of refractory urge incontinence due to detrusor overactivity (both sexes)**

Author	Idiopathic overactivity	Good results
Swami et al [306]	17	12
Leng et al. [307]	8	7
<b>TOTAL</b>	<b>25</b>	<b>19 (76%)</b>

**Table 15. Enterocystoplasty for treatment of refractory urge incontinence due to detrusor overactivity (males and females)**

Authors	Detrusor overactivity	Good or moderate result	Bowel segment
Hasan et al., 1995 [308]	33	19	46 ileum 2 colon
McInerney et al., 1995 [309]	50	44	
Bramble, 1982 [310]	15	13	13 colon 2 ileum
Sethia et al. 1991 [311]	11	9	ileum
Mundy and Sthephenson 1985 [312]	40	30	ileum
Leng et al, [307]	2	2	
Edlund et al [313]	25	19	
<b>Total</b>	<b>176</b>	<b>136 (77 %)</b>	

Table 16. Enterocystoplasty results for reduced bladder capacity

Authors	Bilharziasis cystitis		Tuberculous cystitis		Radiation cystitis		Unknown cause	
	Total	Success	Total	Success	Total	Success	Total	Success
Smith et al. [315]	-	-	7	4	9	3	12	7
Kerr et al. [316]	-	-	12	12	-	-	-	-
Zinman and Libertino [317]	-	-	2	2	1	?	1	1
Dounis et al. [318]	-	-	31	27	-	-	1	1
Lunghi et al. [319]	-	-	15	15	4	4	3	3
Shawket and Muhsen [320]	8	8	-	-	-	-	-	-
Whitmore and Gittes [321]	-	-	7	7	-	-	2	1
Chan et al. [322]	-	-	-	-	-	-	10	9
Shirley et al [323]	-	-	10	10	4	2	-	-
Goodwin et al. [324]	-	-	3	2	-	-	3	3
Winter and Goodwin [325]	-	-	1	1	3	1	-	-
Fall and Nilsson [326]	-	-	1	1	-	-	1	1
Goldwasser and Webster [327]	-	-	-	-	-	-	7	7
Weinberg et al. [328]	-	-	2	2	1	1	1	1
Novak [329]	-	-	11	11	-	-	-	-
Sayegh and Dimmette [330]	2	0	-	-	-	-	-	-
Beduk et al. [331]	-	-	-	-	-	-	1	1
Kuo [332]	-	-	-	-	1	1	-	-
Kawamura et al. [333]	-	-	-	-	-	-	1	1
Hradec [334]	-	-	-	-	27	23	-	-
Lima et al. [335]	-	-	1	1	-	-	-	-
El Otmány et al. [336]	-	-	1	1	-	-	-	-
Yamada et al. [337]	-	-	1	1	-	-	-	-
Miyano et al. [338]	-	-	-	-	-	-	1	1
<b>TOTAL</b>	<b>10</b>	<b>8 (80%)</b>	<b>105</b>	<b>97 (92%)</b>	<b>50</b>	<b>35 (70%)</b>	<b>44</b>	<b>37 (84%)</b>

due to other tissue damage in the surgical area. New conformal techniques for radiotherapy may improve results in the future, so that the need for augmentation decreases.

Almost all of these studies do not distinguish bowel segments or separate males from females in reporting results. Therefore, it is not possible to correlate any particular aspect with the chance of success or failure. However, overall the results seem reasonably good with the exception of radiation. **(Level of evidence 3; Grade of recommendation C)**

## XI. URETHROCUTANEOUS AND RECTOURETHRAL FISTULAE

Urethrocutaneous or rectourethral fistula may have congenital, inflammatory, neoplastic or traumatic origin. It is important to recognize the varying etiology because each type may require different surgical strategy. All reports are still only retrospective case series **(Level of evidence 3; grade of recommendation C)**.

### 1. URETHROCUTANEOUS FISTULA (UCF)

#### *a) Acquired UCF*

Hidden foreign bodies have been described as a rare cause of both strangulation of the glans penis and urethrocutaneous fistula. Tash and Eid [339] presented the case of a 30-year-old man who developed a urethrocutaneous fistula and penile shaft necrosis after a condom broke during intercourse. Neither the patient nor several physicians could identify the retained ring of condom, which had been buried under newly epithelialized skin. He underwent removal of the foreign body under general anaesthesia, followed 5 months later by a formal urethrocutaneous fistula repair.

Urethroperineal fistula, as a complication of open perineal prostate cryosurgery, occurs as an immediate perioperative complication in 10.7% [340]. Thomas et al. retrospectively evaluated 250 patients after radical perineal prostatectomy and revealed only 1 (0.4%) urethroperineal fistula [341].

Fahal et al. [342] published an unusual complication of *mycetoma*. The patient had an infection with *Actinomyces madurae* that involved abdominal wall, perineum and urethra. This resulted in urinary extravasation with a urethrocutaneous fistula.

#### *b) Management of UCF*

The diagnosis of UCF is made by physical examinations and retrograde urethrography, urethroscopy, fistulography, urethral ultrasound or color Doppler imaging. Urethral sonography provides additional information about an involvement of the surrounding tissue, location of vessels and associated abnormalities such as a periurethral abscess [343].

Treatment of UCF usually requires urethroplasty techniques with modifications involving fistula excision and multiple layer closure [344] **(Level of evidence 3; Grade of recommendation C)**

### 2. RECTOURETHRAL FISTULAS (RUF)

Culp and Calhoon described five basic groups of RUF according to the etiology [345]: congenital, iatrogenic, traumatic, neoplastic, and inflammatory.

#### *a) Congenital RUF*

Endo et al. [346] described the results of the Japanese Study Group of Anorectal Anomalies (JSGA) to determine the relative incidence of specific types of these anomalies in Japan. They included discussion of RUF regarding the relationship between the fistula levels and blind end of the rectum, low type deformity, rare types, and associated anomalies. A total of 1,992 patients (1,183 boys and 809 girls) registered from 1976 to 1995 were analysed according to the pathogenesis of anorectal malformation in the field of molecular genetics. They reported that more than 20% of RUF should be categorized as intermediate or low deformity from the position of the rectal pouch. A significant preponderance of Down's syndrome in the deformities without fistulae suggests that investigation of associated anomalies and congenital diseases may provide further insights.

The purpose of Rintala's study was to compare the long-term outcome of sacroperineal-sacroabdominoperineal pull-through (SP-SAP) to that of posterior sagittal anorectoplasty (PSARP). In boys with high anorectal anomalies, PSARP was superior to SP-SAP pullthrough in terms of long-term bowel function and faecal continence [347].

#### *b) Acquired RUF*

Badalament et al. [348] managed one patient (0.4%) with a urethrorectal fistula after cryoablation therapy for prostate cancer.

Benčekroun and co-workers [349] report a series of 11 urethrorectal fistulas observed over a 25-year per-

iod. The aetiologies were surgical trauma (5 cases), fracture of the pelvis (2 cases), inflammatory lesions (3 cases), and one fistula was congenital. Colostomy was performed in 2 patients, surgical closure of the fistula was performed in 7 patients, via an abdominoperineal (3 cases), perineal (2 cases), transperitoneal (1 case) or transanosphincteric incision (1 case).

In 1972 Smith and Veenema [350] reported their 20-year experience with 160 patients undergoing radical retropubic prostatectomy (RRP) with the incidence of 15 rectal injuries. Only 4 fistulas developed in this group.

The most common single cause of RUF in the series of 23 male patients published by Tiptaft et al. [351] was a fracture of the pelvis and iatrogenic causes (two cases after transurethral prostatic surgery, two cases after open prostatectomy, and three cases after urethral instrumentation (**Table 17**). Noldus et al. [352] reported 23 (3.9%) rectal injuries during 589 RRP and cystoprostatectomy. Eastham and Scardino [353] summarized the incidence of rectal injury during RRP in 3834 patients with an average of 0.7% (range 0.2-2.9%). The incidence of RUF, as an immediate perioperative complication of open perineal prostate surgery, is 1.4 %.

Nyam et al. [354] reviewed records of all patients who were diagnosed with rectourethral fistulae between January 1981 and December 1995 and 16 males were identified. All patients were interviewed by telephone for follow-up. The mean age was 68 years and the mean follow-up was 80 months. Ade-

nocarcinoma of the prostate in 15 patients and recurrent transitional cell carcinoma of the bladder in one patient were the underlying malignant diseases. Nine patients had had a RRP with 2 after radiation, 2 after brachytherapy, and 3 after a combination of radiation and brachytherapy. One patient formed a fistula after cystectomy and dilation of a stricture. This heterogeneous group of patients received multiple therapies including initial colostomy (7 patients), transanal repair (2 patients), parasacral repair (2 patients), transperineal repair (2 patients), coloanal anastomosis (3 patients), and muscle transposition (3 patients). Four of the patients required a permanent stoma.

Zippe [355] reviewed preliminary results of prostate cryosurgery and reported a 2 to 5% incidence of RUF. Porter [340] found a 2.5% rate of RUF in 210 patients after TRUS-guided prostate cryosurgery and no urethroperineal fistulae.

Montorsi et al. [356] reported a prostaticorectal fistula after transrectal prostatic hyperthermia (43 degree C) in patients with advanced prostatic cancer after multiple treatment sessions. The fistula was cured after a urethral catheter was left in place for one month.

Kleinberg et al. [357] summarized results of 31 patients with stage T1 or T2 prostatic carcinoma following CT guided transperineal (125) I implants and reported that only one patient developed a prostaticorectal fistula that was managed with an ileal conduit.

Fengler and Abcarian [358] published their experience of eight patients with recto-urinary fistulae in the course of treatment of prostate cancer (3 fistulae after radiation therapy alone, 3 after prostatectomy and 2 after both surgery and radiation therapy).

Chang et al. [359] published a case of prostatic malakoplakia masquerading as a rectal tumor due to formation of a fistulous tract to the rectal muscular layers. Cools et al. [245] reported a very uncommon type of fistula between the large bowel and the prostatic urethra due to Crohn's disease. Felipetto et al. [360] described a prostaticutaneous fistula as a complication of pseudomonas prostatitis.

### c) *Diagnosis of RUF*

RUF may be strongly suspected from the patient's history (fecaluria, abnormal urethral discharge, pneumaturia, leakage of urine from the rectum during micturition). Rectal examination, proctoscopy, careful urethroscopy, intraurethral injection of methylene blue dye, radiopaque contrast agent pla-

**Table 17. Causes of Rectourethral fistulae in 23 patients (Tiptaft [351])**

Fractured pelvis with ruptured urethra	11
Direct trauma	2
Secondary to urethral stricture and sepsis	3
Tuberculosis	1
Iatrogenic	12
Iatrogenic causes	
Urethral instrumentation	3
Transurethral prostatic surgery	2
Open prostatectomy	2
Flap urethroplasty	1
Colo-anal anastomosis	1
Abdominoperineal resection of rectum	1
Radiation therapy	2

ced into the bladder and then voided usually appears in the rectum on X-ray, are the most important diagnostic steps [343, 361].

#### **d) Therapy of RUF**

Small fistulae may resolve spontaneously with urinary and/or fecal diversion. Therefore, an initial trial of conservative therapy is reasonable. Selected patients with chronic fistulas who are poor surgical candidates may also be managed conservatively with antibiotics, pads and symptomatic care. Timing of repair is often individualized, mainly according to the etiology, delay in diagnosis, size of fistula, whether it is the first or subsequent repairs, and the general condition of patient.

Diversion of urine (suprapubic cystostomy) is generally recommended as well as correction of any urethral stricture distal to the fistula. Fecal diversion, with colostomy is used by some as a mandatory part of double diversion or selectively by others. Gibbons [362] stressed the need for a diverting colostomy for 3-4 months.

However, as surgeons obtained more experience, bowel preparations became standardized, and effective antibiotics were developed, the enthusiasm for colostomy diminished. Currently, colostomy is recommended in circumstances where antibiotics alone cannot control the inflammation and infection associated with the fistula or when the fistula involves radiated tissue. Low residue diet is also useful for healing. Suitable drainage (perineal and urethral splinting) is stressed. Two-layer closure of the urethra and rectum with suture lines at right angles and with interposition of soft tissue (eg. omentum [363], gracilis muscle [363], or scrotal flap [365]) has been described. Surgical approaches include transabdominal, transvesical, or direct exposure of the RUF.

#### **e) Surgical Approaches**

Stephenson and Middleton [366], modified the York-Mason repair and reported their experience with posterior sagittal, transanal, transrectal repair of RUF in 15 patients. The transsphincteric, transanal surgical approach provides many advantages, including easy access and identification of the fistula tract, good surgical exposure, adequate resection to well vascularized tissue, and access to several vascularized flaps for interposition between the repaired urinary and gastrointestinal tracts.

Culkin [367] reported preliminary experience with

the transsphincteric, transanal surgical approach to correct acquired urethrorectal fistula in five men. Mean patient age was 56.6 years (range 37 to 72). The etiology was surgical (radical prostatectomy) in 3 cases, traumatic in 1 and idiopathic in 1. The time from the diagnosis of urethrorectal fistula to surgery was 4 weeks to 4 years. Five men underwent excision and closure of a urethrorectal fistula with diverting colostomy. In 4 men (80%) urinary continence subsequently returned with adequate sphincter tone, while in 1 (20%) with perineal trauma and active proctitis the fistula recurred 6 weeks after surgery.

The surgical approaches including the numbers of reported patients are listed in **Table 18** [345, 349-352, 358, 361, 365-382].

### **1. PERINEAL**

In 1926, Young [368] dissected the rectum away from sphincters, divided the fistula, closed the urethra, and mobilized the rectum further cephalad in such a fashion as to pull the affected rectum caudally out of the anus where it was then transected and discarded, suturing the proximal rectum to the anal skin. Subsequently Lewis, in 1947 [369], described suturing the levator muscle fibers together in the anterior midline when possible.

Goodwin et al. [370] reported a series of 22 RUF approached perineally. They extensively mobilized the rectum posteriorly and the bladder anteriorly through wide perineal exposure allowing interposition of the levator ani muscles between the urinary tract and rectum.

### **2. POSTERIOR SAGITTAL**

Kraske in 1885 [383] described a posterior midline incision extending to the left paramedian aspect of the coccyx and sacrum that involved partial removal of the sacrum in addition to coccygectomy. His method did not involve division of the sphincters, but rather sweeping the rectum laterally to ultimately facilitate resection and reanastomosis of a tumour-bearing rectal segment, thereby preserving fecal continence. In 1962, Kilpatrick and Thompson [373] used this approach when the rectum was completely mobilized circumferentially proximal and distal to the fistula. The RUF was then divided, sparing as much as possible on the urethral aspect. The rectal part of the fistula was excised and closed in two layers, and the urethra was repaired and stented with a catheter.



*Table 18. Surgical approaches to rectourethral fistulas*

<b>APPROACH</b>	<b>AUTHOR, YEAR</b>	<b>No. PTS</b>
<b>PERINEAL</b>	Young, 1926 [368]	11
	Lewis, 1947 [369]	13
	Goodwin, 1958 [370]	22
	Culp and Calhoon, 1964 [345]	20
	Smith and Veenema, 1972 [350]	4
	Youssef, 1999 [371] ( <i>perineal dartos flap</i> )	12
	Benchekroun, 1999 [349]	11
	Ng, 2004 [372] ( <i>buccal graft</i> )	27
<b>POSTERIOR - SAGITTAL</b>	Kilpatrick and Thompson, 1962 [373]	6
	Stephenson, 1999 [366]	15
<b>POSTERIOR – TRANSSPHINCTERIC</b>	Kilpatrick and Mason, 1969 [374]	7
	Culp, 1964 [345]	20
	Fengler, 1997 [358]	8
	Fournier, 1996 [375]	1
	Bukowski, 1995 [376]	7
<b>TRANSANAL</b>	Vose, 1949 [377]	4
	Parks and Motson, 1983 [378]	1
	Tiptaft, 1983 [351]	3
	Noldus, 1997 [352]	5
	Culkin, 2003 [367]	5
<b>COMBINED</b> ( <i>posterior transsphincteric anterior rectal wall advancement</i> )	Al-Ali, 1997 [361]	16
<b>ANTERIOR TRANSANORECTAL</b>	Geceleter, 1973 [379]	19
	Venable, 1989 [365]	1
	Zinman, 2003 [380]	22
<b>ENDOSCOPIC</b>	Wilbert, 1996 [381]	2
	Bardari, 2001 [382]	1

### 3. POSTERIOR (PARASACROCOCYGEAL) TRANSSPHINCTERIC

In 1969 Kilpatrick and Mason [374] updated this method and advocated a more radical method of dividing the rectal sphincters to give direct access to the RUF. The procedure (the York-Mason approach) is simpler than some complicated transabdominal or transperineal approaches to RUF. It is still used because it allows direct visualization of the fistula via parasacrocoxygeal (transsphincteric) incision especially to fistulae in the mid to lower rectum [358]. After the skin incision the mucocutaneous junction is marked with sutures and the internal sphincter is exposed. Division of the sphincter mechanism and posterior rectal wall allows exposure of the fistula. Each sphincter muscle is tagged with color-coded sutures. The next step of this procedure is the incision around fistula, followed by excision of the fistulous tract exposing the catheter in prostatic urethra. The undermining of rectal wall allows sufficient mobilization. After closure of prostatic urethra it is recommended to close the full-thickness rectal wall flaps in a “vest over pants” technique (**Figure 3**). It is important to note that the suture lines do not overlie each other. The procedure is completed by suture of rectal wall and approximating the sphincter muscles (**Figure 4**). Fengler and Abcarian [358] reported healing of RUF in all of 8 patients with the York-Mason approach. Bukowski et al. [376] managed 7 acquired recurrent RUF (3 after prostatectomy, 3 after trauma and 1 after perineal abscess) using York-Mason technique and similar experience was described by Fournier et al. [375] in the management of a case of the urethro-prostato-rectal fistula after a gunshot wound.

### 4. TRANSANAL

Parks and Motson [378] popularized the addition of a full thickness local flap of anterior rectal wall as an adjunct to fistula repair through the intact anal canal (**Figures 5** [384] and **6**). They modified the transanal technique by denuding the rectal mucosa lateral and distal to the fistula, and mobilized the rectal wall away from Denonvilliers’ fascia proximal to the fistula for four centimeters. Tiptaft et al. [351] also used a special anal retractor for this surgery.

With the Latzko procedure the RUF is closed in three layers with absorbable suture. A transurethral catheter is placed for 3 weeks. Noldus et al. [352] reported 23 patients (3.9%) with rectal injury during 589 RRP and cystoprostatectomy. Of these 23 patients,

12 developed a RUF. Seven fistulas closed spontaneously with prolonged catheter drainage. The remaining 5 fistulas were all successfully closed with the transanal Latzko procedure.

Al-Ali et al. [361] treated 30 men with RUF caused by war wounds. He used the method of posterior transsphincteric anterior rectal wall advancement as the treatment of choice. Double diversion (end sigmoid colostomy and suprapubic cystostomy) for one month was performed in all patients. Double diversion alone resulted in ‘spontaneous’ RUF healing in 47% of patients but 53% required reconstruction. Early repair was recommended for large fibrous fistulas. Undiversion was done after two months when the urethra and anorectal canals were normal.

### 5. ANTERIOR TRANSANORECTAL

In 1973 Gecelter [379] performed a midline perineal incision to gain access to the urinary tract after placing the patient in exaggerated lithotomy position. The sphincter was incised anteriorly, tag sutures carefully placed, and the rectal incision was carried to the fistulous tract, which was excised and repaired in multiple layers with transposition of tissue as available.

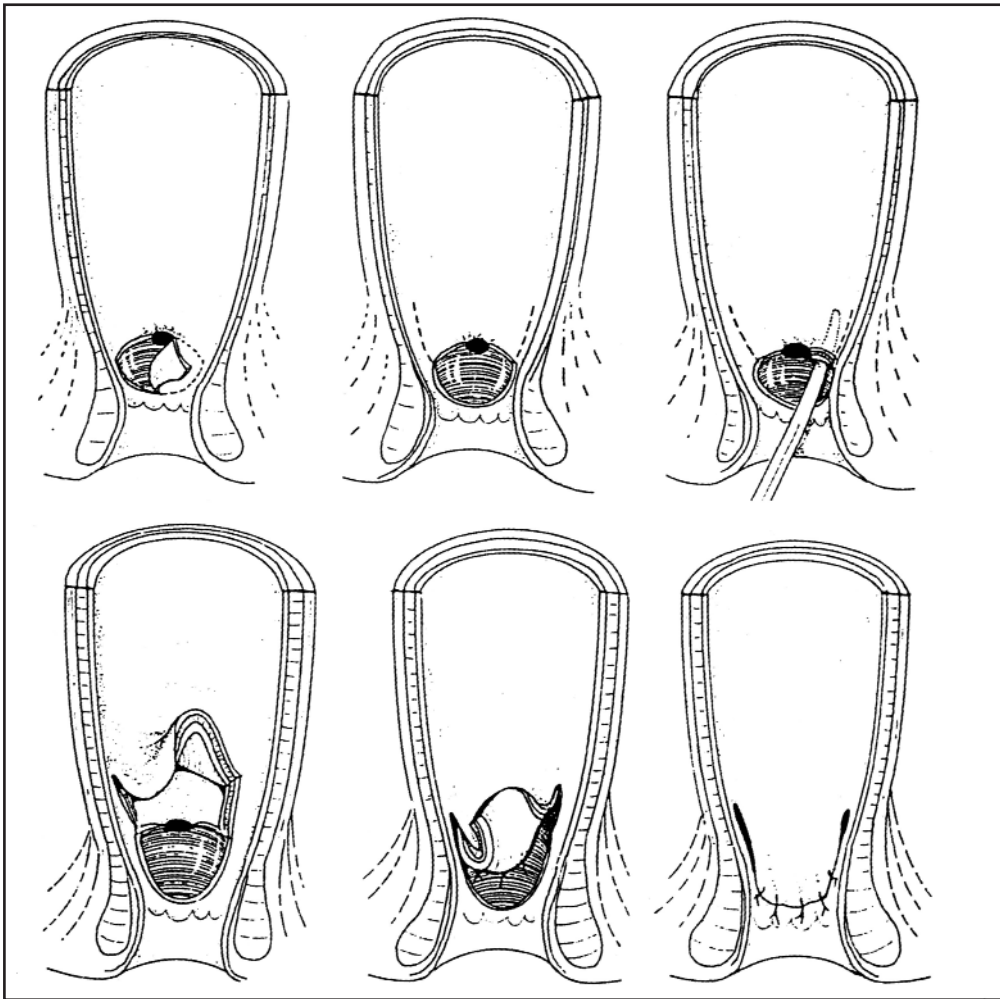
### 6. ENDOSCOPIC

Wilbert et al. [381] reported two patients with RUF who were repaired endoscopically transanally. The patients were positioned prone and the rectoscope mounted to the operating table was inserted into the rectum. The fistula was visualized and the opening excised to the level of the perirectal tissues with cautery. The rectal wall was mobilized full thickness with scissors and closed primarily in two layers with a microscope. The patient was then placed in lithotomy position and the urethral side of the fistula was coagulated and injected with fibrin.

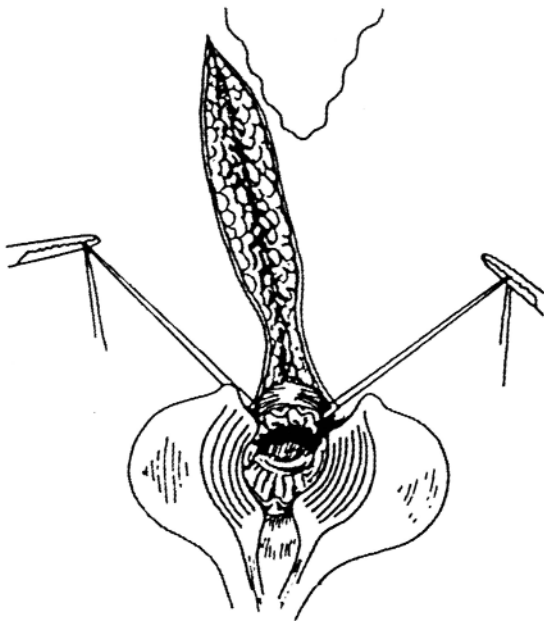
Recently Bardari et al. [382] used cyanoacrylic biological glue to close one prostatico-perineal fistula complicating an abdominoperineal resection of rectum and one persistent neobladder-ileal fistula. The biologic sealant was administered endoscopically through an open-end 6F ureteral catheter.

### 7. OTHER MODIFICATIONS

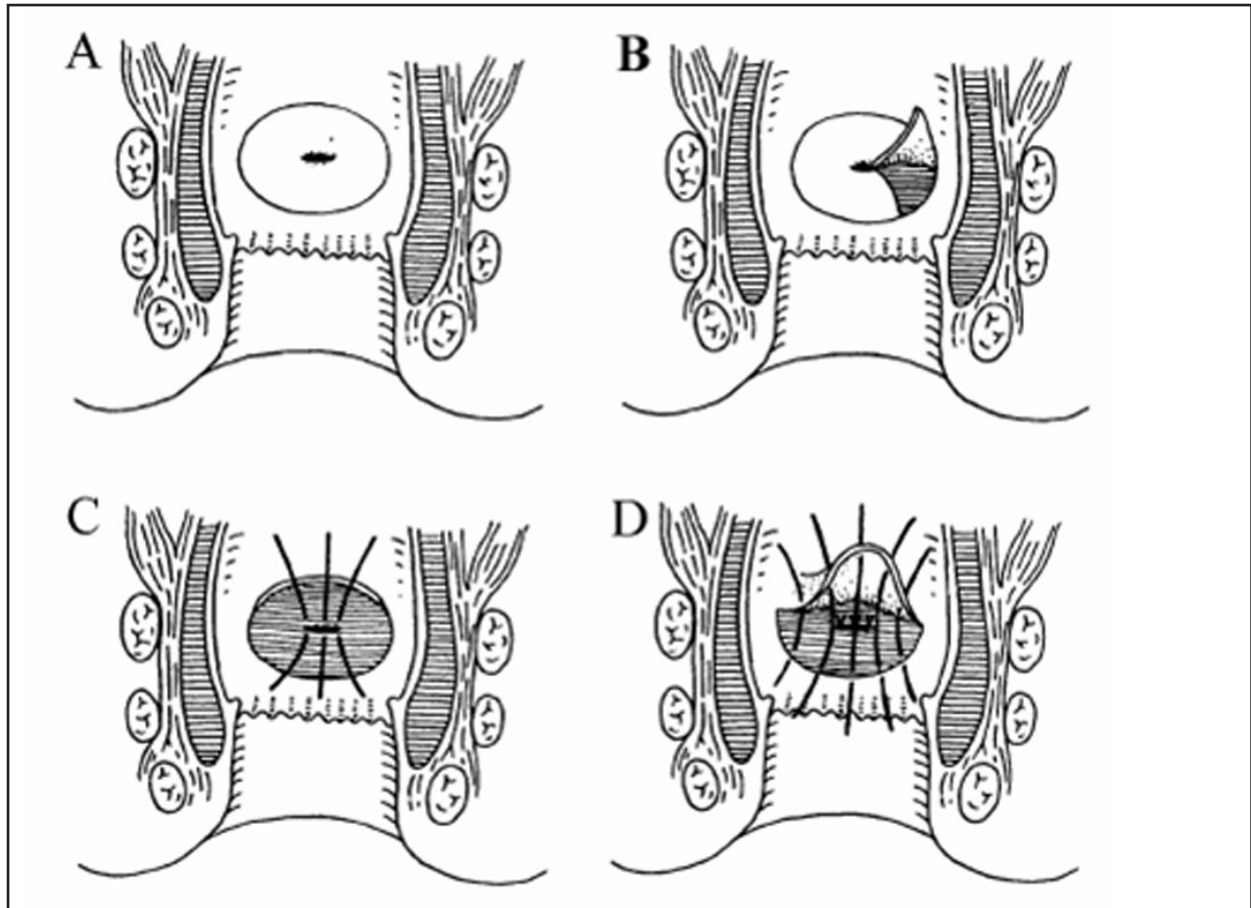
Youssef et al. [371] successfully treated 12 male patients who presented with RUF from 1990 to 1997 using the perineal subcutaneous dartos flap procedure. The RUF resulted from crush pelvic injury in 6 cases, gunshot wounds in 2, and post prostatectomy



*Figure 3. Rectourethral fistula repair. Full thickness rectal wall is mobilized to close in a “vest over pants” technique to close the fistula.*



*Figure 4. York-Mason approach to a rectourethral fistula via a parasacroccygeal (transsphincteric) incision. Sutures are used to mark the sphincters. The speculum has been placed at the bottom of the incision and the anterior rectal wall is visible.*



**Figure 5.** Transanal repair of rectourethral fistula [384]. **A.** Elliptical incision of the rectal mucosa around the fistula. **B.** Denudation of the rectal mucosa. **C.** Fistula closed with absorbable suture. **D.** Rectal mucosal flap sutured with absorbable suture.

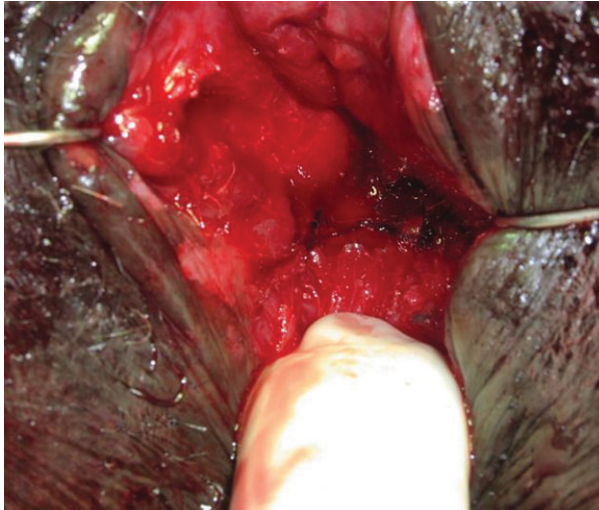


**Figure 6. A.** Retrograde urethrogram of a 55 year-old man who underwent a radical prostatectomy. He complained of fecaluria and urine per rectum. This shows urethral contrast in the rectum through a rectourethral fistula.

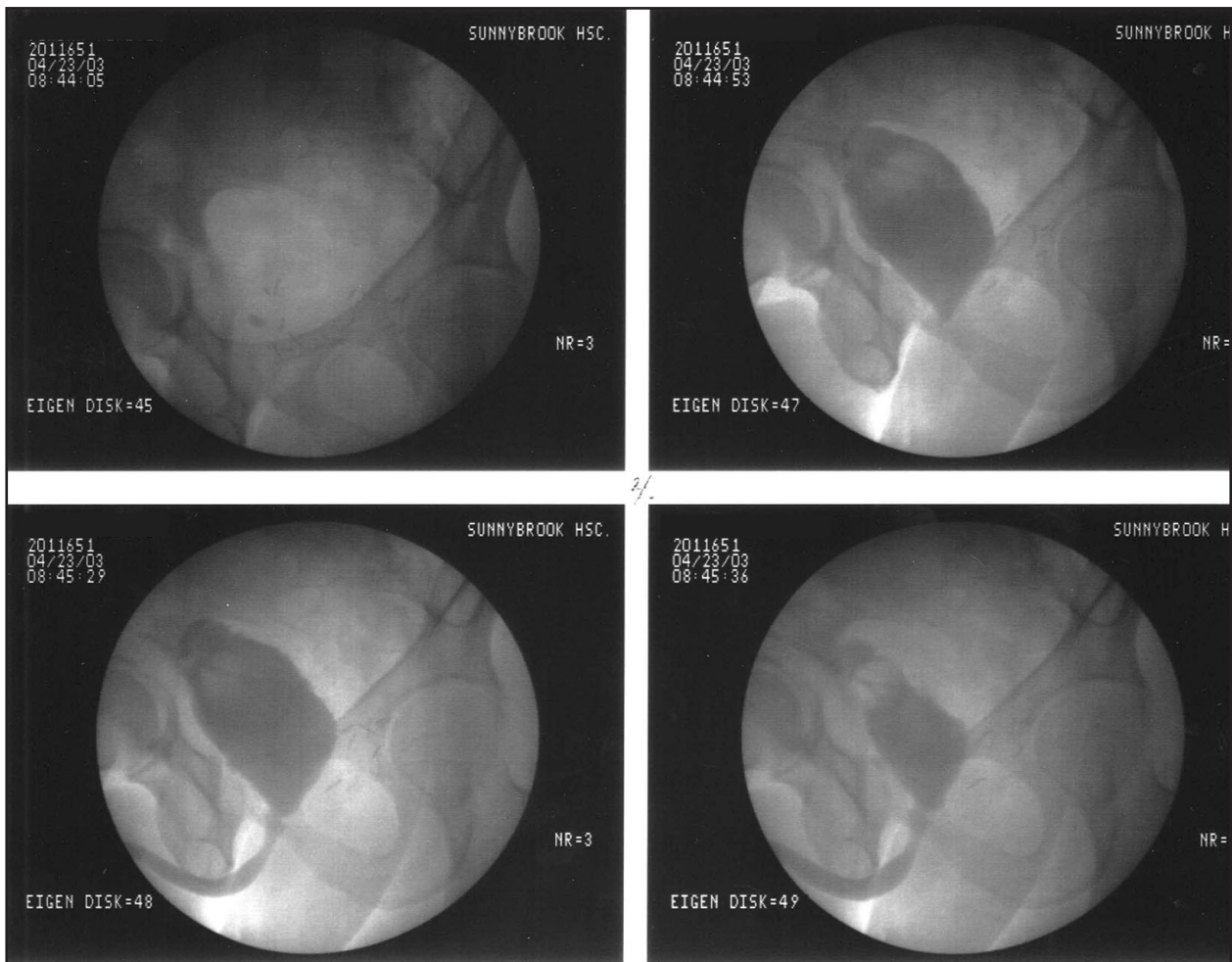


**Figure 6. B.** Intraoperative photograph of transanal rectourethral fistula repair. The anus is held open by the ring retractor to permit direct access to the fistula.





*Figure 6. C. Intraoperative view of the rectal mucosal sutures in the rectourethral fistula repair.*



*Figure 6. D. Retrograde urethrogram 3 months after transanal rectourethral fistula repair. There is no contrast entering the rectum from the urethra. The patient's suprapubic tube was removed and his colostomy was reversed.*



in 4. The fistula was associated with a urethral stricture in 4 cases. A perineal approach was used and combined with a transsymphyseal approach in the 4 patients with posterior urethral stricture. They interposed a subcutaneous dartos flap as a tissue flap between the repaired rectum and urethra. No leakage or perineal collection developed and there was no fistula recurrence. Follow-up ranged from 9 to 42 months. This technique of a perineal subcutaneous dartos flap may fulfill the principles for successful repair of RUF.

Felipetto et al. [360] closed a prostatico-cutaneous fistula (as a complication of pseudomonas prostatitis) with human fibrin sealant (Tissucol). Venkatesh and Ramanujam[385] prospectively studied the efficacy of autologous fibrin glue application for closure of recurrent anorectal fistulas. Overall success rate was 60 percent however patients with fistulas associated with acquired immunodeficiency syndrome and the urinary tract failed to respond.

#### *f) Summary*

A review of recent literature shows an increasing number of papers describing treatment. All available studies are retrospective cases and case series. There are many causes of these fistulas described in the literature but there is a lack of valid epidemiologic data about the incidence of UCF and RUF. The diagnostic algorithm has not changed in many years.

The aim of the surgical approach is the closure of all types of fistulas. While spontaneous closure and success with a one-stage procedure has been reported most cases to date involve 3 stages (double diversion, closure technique, and undiversion). An endoscopic approach using biological sealants is promising. Only a few urologists and general surgeons have gained wide experience in the management of UCF or RUF. No single procedure has yet proved to be best or universally applicable. **(Level of evidence 3; grade of recommendation C)**

## **XII. THE ARTIFICIAL URINARY SPHINCTER (AUS)**

Different devices designed to control urinary incontinence in the male go back to the middle of the 18th century [386]. Since then research eventually produced external and implantable devices. The gold standard today is considered to be the artificial urinary sphincter (AUS) designed by F.B. Scott, W.E. Brad-

ley, and G.W. Timm in 1973 [387]. The original model underwent a number of modifications, but the basic principle remained the same. It consists of a fluid filled hydraulic system with a cuff around the urethra, a pressure regulating balloon and an activating device, the pump, placed in the scrotum.

### **1. AVAILABILITY AND COST**

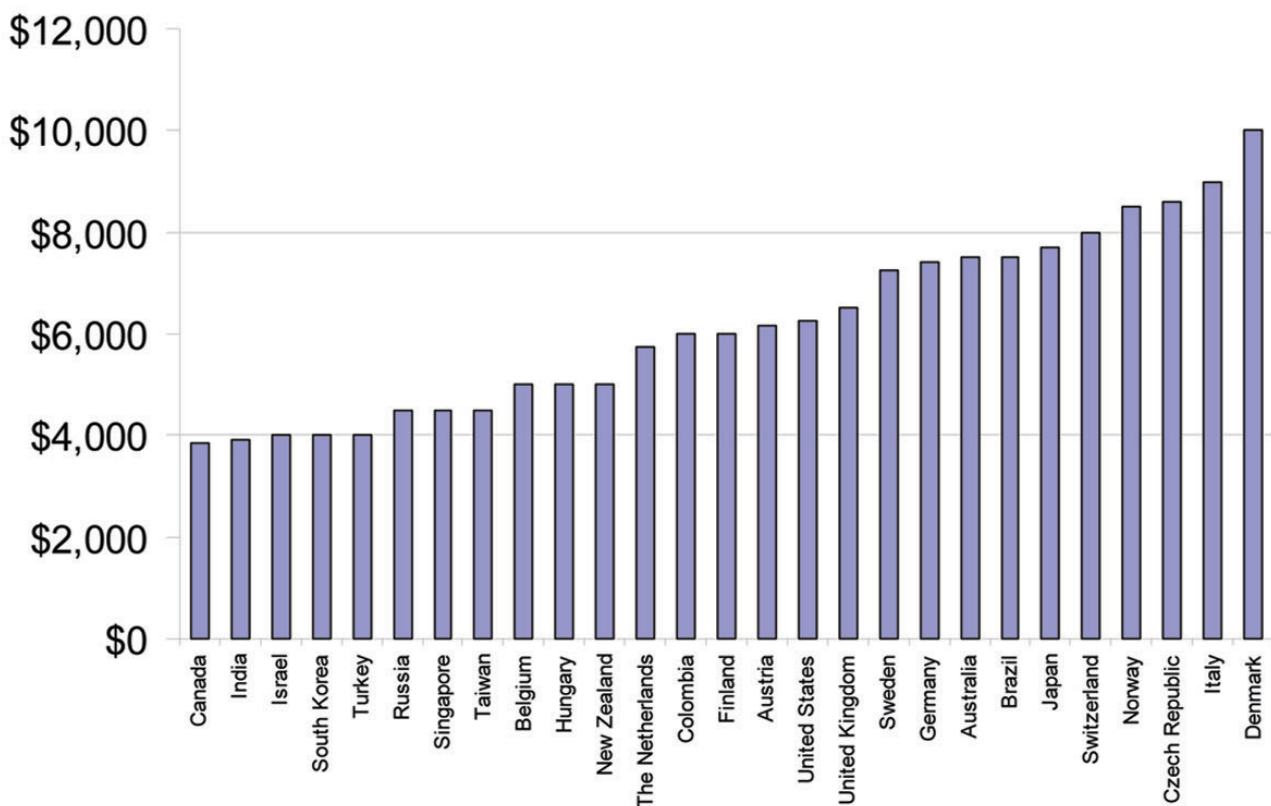
We recently conducted an e-mail survey among urologists and gynecologists, members of the International Continence Society asking them if the AUS was available in their country; and if so, what was the price of the device (in US dollars). About 10% of the members responded by email from 31 countries. According to the responders, in at least 4 countries (Georgia, Hong-Kong, Romania and Saudi Arabia) the device was not available. Furthermore, in some countries, even if the device is marketed, its high price precludes its use, as in the Czech Republic and Hungary. The price varies even within the same country (**Table 19**). The cost variability among countries is shown in **Figure 7**. Very few gynecologists implant the sphincter, probably because the majority of patients receiving the device are male. Although the response to the survey was low and the results may not be scientifically valid they do show substantial variability and give an idea of the current international situation.

### **2. INDICATIONS**

The indication for implantation of an AUS in the male – as in the female – is urinary incontinence to a degree that affects the patient's quality of life. In the vast majority of male patients incontinence is secondary to a prostatectomy; neurogenic bladder dysfunction is the second most frequent etiology. Previous radiotherapy to the pelvic is not a contraindication [388]. The ultimate outcome seems to be similar in patients whether or not they have received radiation therapy [148], although a higher incidence of urethral atrophy, erosion and infection requiring surgical revision has been reported in irradiated patients compared to those not irradiated (41% vs 11%). Despite this observation, long term continence and patient satisfaction appear not to be adversely affected in the irradiated patient [148]. Patients voiding with Valsalva maneuvers because of an idiopathic underactive or neurologically acontractile bladder, do not seem to be at an increased risk of complications [389]. It should also be noted that patients with previous anti-incontinence procedures show a significantly higher explantation rate [390]. Clinical

*Table 19. Cost of the AMS 800 artificial urinary sphincter in 29 different countries, data from a survey among urologists and gynecologists, members of the International Continence Society. (Prices in US dollars)*

COUNTRY	PRICE	COUNTRY	PRICE
Austria	5,300 – 7,000	Japan	5,400 – 10,000
Australia	7,000 – 8,000	New Zeland	5,000
Belgium	5,000	Norway	7,000 – 10,000
Brazil	3,000 – 12,000	Russia	4,500
Canada	3175 – 4555	Singapore	4,500
Colombia	6,000	South Korea	4,000
Czech Republic	8,600	Sweden	6,000 – 8,500
Denmark	10,000	Switzerland	8,000
Finland	6,000	Taiwan	4,500
Germany	5,000 – 9831	The Netherlands	2,500 – 9,000
Hungary	5,000	Turkey	4,000
India	3,900	United Kingdom	5,000 – 8,000
Israel	4,000	United States	4,000 – 9,000
Italy	7,000 – 11,000		



*Figure 7. Graph showing range of costs of the Artificial Urinary Sphincter in various countries.*

experience suggests that enterocystoplasty or gastrocystoplasty can be done simultaneously with the implantation of the AUS [391, 392]. AUS can also be implanted in patients after bladder substitution [212], and in those with locally recurrent prostate cancer with a relatively good prognosis [393], or those with severe post-radical prostatectomy bladder neck contracture in whom a stent has been placed previously [219].

### 3. SURGICAL TECHNIQUE:

The original technique of implantation is illustrated in **Figure 8**. The cuff of the sphincter around the bulbous urethra is placed via a midline perineal incision, while the pressure regulating balloon and the scrotal pump are inserted via a separate inguinal incision.

More recently a new surgical approach has been described using a single, upper transverse scrotal incision which allows the placement of all 3 components of the system, the cuff, the pump in a scrotal pouch, and the reservoir behind the fascia transversalis [394]. The procedure is claimed to be easier and faster to complete. Caution should be exerted, however, before this approach is universally adopted, because the placement of the cuff at the *proximal* part of the bulbous urethra seems to be more difficult, and no long term results are available at this time [395].

One of the pitfalls during surgery is laceration of the urethra when dissecting it from the corpora cavernosa where no real anatomical plan exists. Intraoperative recognition of urethral injury can be facilitated by retrograde perfusion sphincterometry using a flexible cystoscope [32].

### 4. COMPLICATIONS

Complications following implantation of the AUS can be divided into the broad categories of incontinence, erosion and/or infection, and unusual complications.

#### a) Incontinence

Incontinence following implantation of an AUS can result from (1) alteration in bladder function, (2) atrophy of the urethra, or (3) mechanical failure of the device. These causes may co-exist.

#### 1. ALTERATION IN BLADDER FUNCTION

This situation has been reported principally in patients with neurogenic bladder dysfunction, especially in children [396-401]. These changes include de novo involuntary detrusor contractions, decrease in bladder compliance, and the development of a

high pressure system, causing incontinence, hydronephrosis and ultimately renal failure. Modifications in detrusor behavior (including its consequences on the upper urinary tract) occur in up to 57% of cases [396-407]. It should be pointed out, however, that there has never been a published report of hydronephrosis following implantation of an AUS for incontinence after prostatectomy [408]. The best candidates for sphincter implantation are those with a low pressure, relaxed, and compliant bladder but an incompetent urethral sphincter [405].

#### 2. ATROPHY OF THE URETHRA

This may occur at the cuff site secondary to long-term mechanical compression of the periurethral and urethral tissues. It is not often reported and some authors do not even mention it as a possible cause of AUS failure [149, 169, 408]. About 4 months following implantation, cuff efficiency diminishes, presumably because pressure atrophy occurs in every patient to some extent [409]. The incidence of urethral atrophy leading to revision varies from 3% to 9.3% [116, 122, 406, 410-413]. This atrophy can be lessened with nocturnal deactivation of the cuff [414].

#### b) Mechanical failure

This includes perforation of one of the components with loss of fluid from the the system, air bubbles or organic debris within the system causing inadequate function of the pump, disconnection of the tubes, or kinking of the tubes. Introduction of "kink-free" tubing has virtually eliminated this last complication. The incidence of these complications varies widely with ranges from 0% [410] to 52.5% [129] with the longest follow-up. In this latter study, the cuff seemed to be the most vulnerable part of the system (22 cuff failures in 18 patients, most of them occurring during the first 2 to 3 years following implantation), followed by pump failure (6 times in 4 patients). Blockage is an exceptional event, occurring only once in 61 patients followed from 10 to 15 years [129]. An unusual mechanical complication has been reported recently. The locking tab became displaced distally into the cycling portion of the cuff preventing the fluid from flowing into the cuff surrounding the urethra [415].

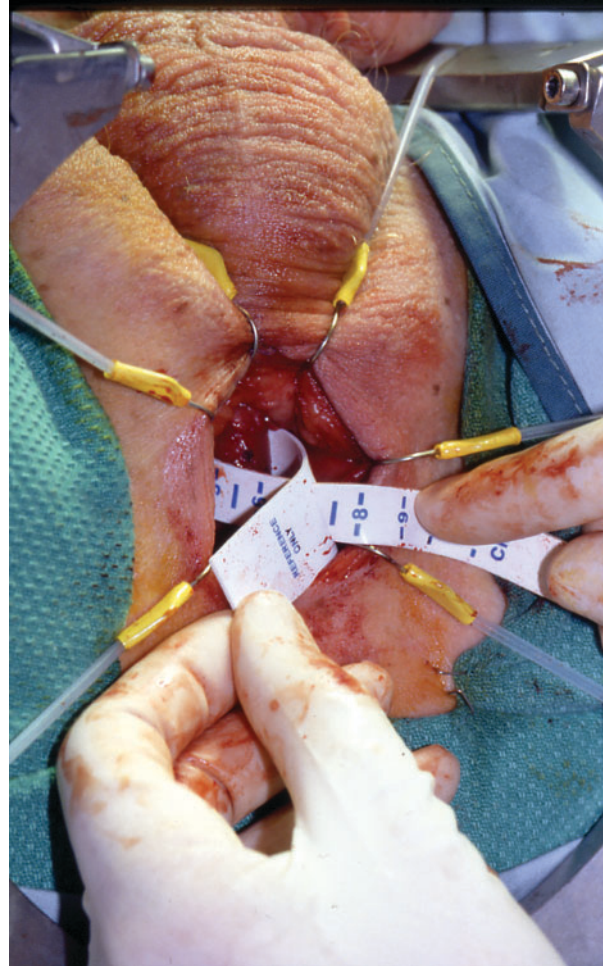
#### c) Erosion and/or infection

Erosion and infection are two major complications that almost invariably necessitate removal of the prosthesis. Their incidence is usually reported as a single complication.

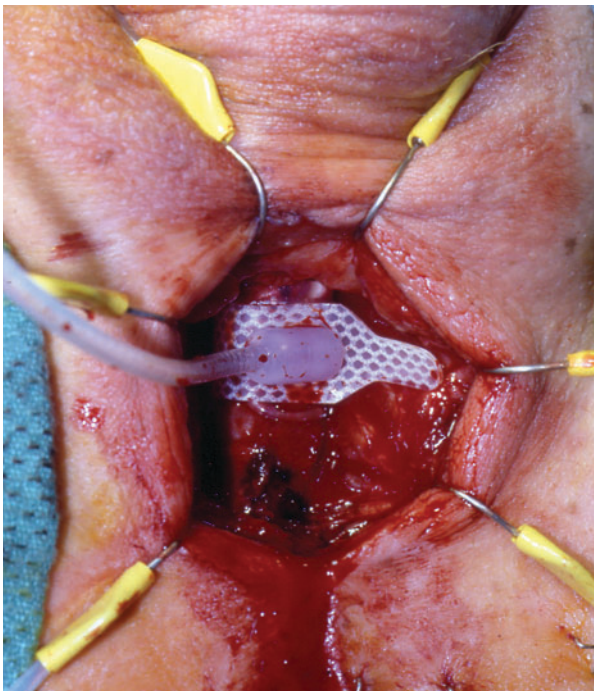




*Figure 8. A. With the patient in lithotomy position, a perineal incision is made behind the scrotum to expose the bulbospongiosus muscle and the bulbourethral urethra.*

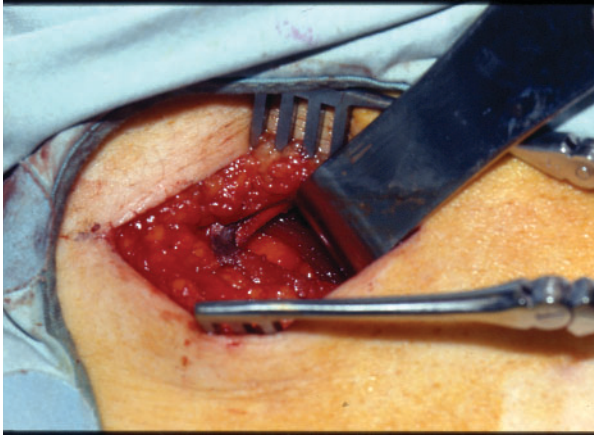


*Figure 8. B. The urethra is mobilized circumferentially within the bulbospongiosus muscle and the measuring tape is used to obtain the cuff size.*

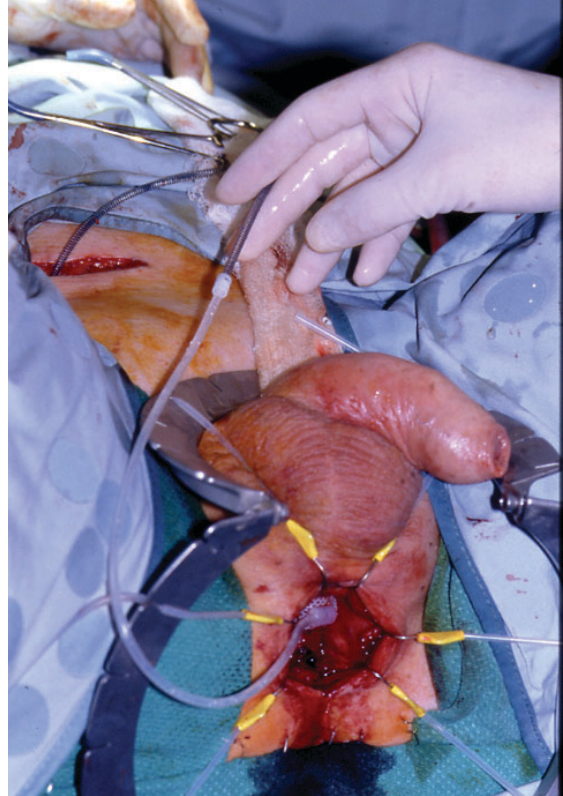


*Figure 8. C. The belt-like cuff is positioned around the urethra.*

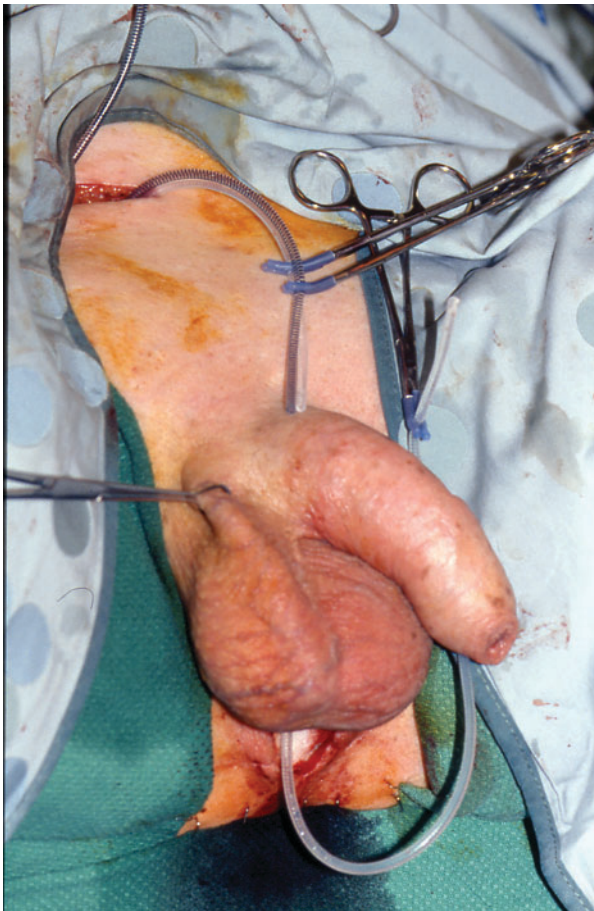




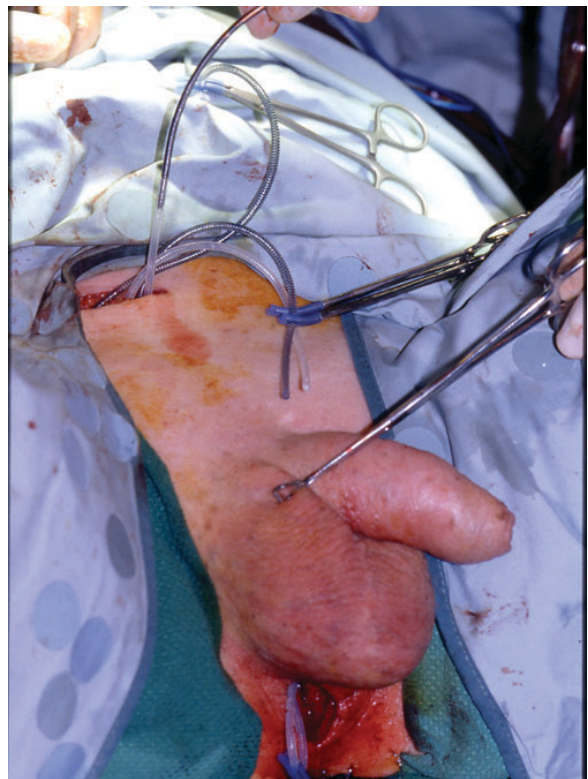
*Figure 8 D. A right lower quadrant (RLQ) abdominal incision is made and the extraperitoneal space is entered lateral to the rectus muscle for insertion of the reservoir.*



*Figure 8 E. After reservoir insertion the cuff is pressurized with fluid*

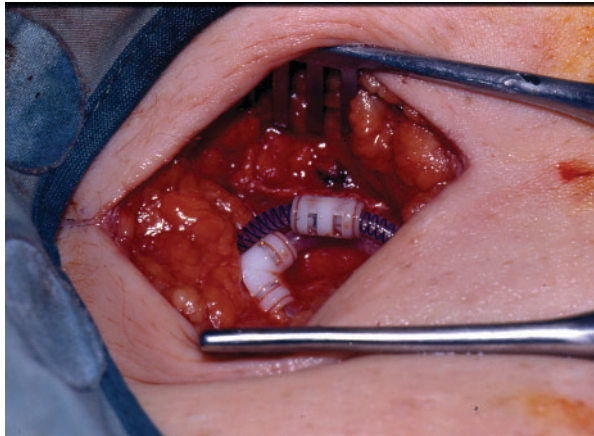


*Figure 8 F. A scrotal space is created under the dartos and the pump is inserted (held with a Babcock clamp).*



*Figure 8 G. The cuff tubing is brought from the perineal incision to the RLQ incision with a tubing passer.*





**Figure 8.** *H Connectors are placed to join the tubes from the cuff and reservoir to the corresponding tubes from the pump in the RLQ incision.*

The incidence of this complication varies from 0% to 24.6% [116, 169, 399, 405, 406, 410-413, 416, 417]. As would be expected, the highest incidence has been reported with the longest follow-up (10-15 years)[116]. Two-thirds of the erosions occurred during the first year. Previous surgery [418] at the site of cuff placement increases the risk of erosion. This, however, can be decreased by delayed activation [419]. Some authors, however, did not find an increased incidence of complications when a new cuff was implanted at the site where several months before a cuff has been removed for infection or erosion [420]. Other risk factors include urethral catheterization and urethral endoscopic manipulations with an activated sphincter in place[421].

As mentioned above, the majority of authors consider that even if previous radiotherapy constitutes a risk factor in terms of increased complication and revision rates, this does not constitute a contraindication for the implantation of an AUS [115, 117, 135, 148, 149, 167, 422]. Patient satisfaction is similar in those who have been irradiated, compared to those who have not been [115, 124, 148], and the degree of satisfaction does not seem to correlate with the number of surgical revisions [128].

#### **d) Rare complications**

Several unusual, although rare complications have been recently reported in the literature, such as the intravesical migration of the reservoir with secondary stone formation in the bladder [423], or a giant urethral diverticulum at the site of a previously removed cuff because of erosion and urinary extravasation [424].

The total number of procedures done in a given center does not seem to be a determining risk factor for complications. Comparable erosion/infection rates have been reported from centers with fewer than 50 or more than 100 cases [137]. This suggests that erosion and infection are more closely related to the physiologic state of the host rather than the experience of the surgical team, provided standard precautions are strictly applied.

## **5. DURABILITY OF AUS COMPONENTS**

When defining durability of one of the components or the AUS as a whole, one should distinguish between explantation of the device due to device malfunction (e.g. leak in one of the components) or complications caused by an otherwise properly functioning sphincter unit (e.g. erosion by the cuff, infection at the site of implantation, etc.). This distinction is rarely made in the literature. Durability of a device is defined as time elapsed during which no mechanical problem alters the normal function of the device. This should exclude the second group from further analysis.

There are very few references in the literature pertaining to the length of time a device functioned normally before its removal due to mechanical failure. In a multicenter trial, for neurogenic bladders, conducted in France [406], the authors mention that the “mean operational life” of the sphincter was 56 months (range 3-118 months). Haab et al [122] analyzed 68 patients and noted that the mechanical failure rate dropped from 44.4% to 12.4% since modifications were made to the device, mainly the cuff component. Survival time of these components was not provided. Similar conclusions can be drawn from a series from the Mayo Clinic [126] where the modification of the cuff design (narrower back) resulted in a significant drop of the reoperation rate at 5 years. In the “narrow back” group 17% (31/184) required reoperation. Mean time to reoperation was 26.2 months (mean 2-68 months). Using Kaplan-Meier statistical analysis for this group of patients, the overall 5 year expected product survival was 75%.

In a review Venn et al [169] analysed the outcome of 100 patients in whom an artificial urinary sphincter was implanted for more than 10 years. Thirty-six percent of them still had the original sphincter and were continent at a median follow-up of 11 years. The bulbar cuff, as compared to the bladder neck cuff provided a slightly better continence rate at 10 years, 92% and 84%, respectively. The lowest erosion rate occurred with the bulbar cuff. Device survi-

val rate at 10 years was 66% in this series.

In a series of 30 boys with spina bifida Spiess et al [425] found that the mean lifetime of all AUS was 4.7 years, with no statistically significant difference in sphincter survival of those inserted at the bladder neck or the bulbous urethra (4.6 and 4.9 years, respectively). A sharp drop was observed at 100 months with only 8.3% of the original sphincters still functioning beyond this point.

It might be useful to consider patients with 'primary adequate function' when no revision is necessary to achieve continence separately from those with 'additional procedure-assisted adequate function', where one or more revisions are necessary to obtain favourable outcome. Klijn et al. [121] showed in their series of 27 men who became incontinent after a radical prostatectomy that at a mean follow-up of 35 months, 81 % of the patients achieved satisfactory continence. The 5 year 'primary adequate function' and 'additional procedure-assisted adequate function' rates, based on the Kaplan-Meier curves, were 49% and 71%, respectively. The median time to failure for the 'primary adequate function' group was 48 months, the median time to definitive failure of 'additional procedure-assisted adequate function' was >72 months.

In the most recent series the global long term (2 to 7.7 years) revision rate, for any of the above mentioned reasons varies between 16% and 50% [127, 128, 426]. Patients with neurological deficit seem to have a higher risk of non-mechanical failure and the overall continence rate may be poorer compared to non-neurologic patients [29].

## 6. DIAGNOSTIC PROCEDURES RELATED TO ARTIFICIAL SPHINCTER FAILURE

The diagnostic evaluation of urinary incontinence after the placement of the AUS is critical for the management of these patients and represents a challenging problem for the urologist. Several diagnostic and management algorithms have been proposed, some relatively simple, others more complex [29, 30, 135, 137, 407, 427-429]. **Figure 9** shows an algorithm to investigate and treat the male patient with a previously functioning AUS who becomes incontinent.

Physical examination should exclude infection at the site of the cuff or the scrotal/labial pump. Difficulty compressing the pump suggests tube kinking, fluid loss or an obstructed system.

Plain X-rays of the abdomen or pelvis may show fluid loss, if the system is filled with radio-opaque solution [430, 431] (Figure 1). It is necessary to obtain a baseline film at the discharge of the patient from the hospital for subsequent comparison because radiographic imaging of the balloon does not detect changes until at least 50% of its volume has been lost [12].

Cystometrogram or complete urodynamic study will demonstrate changes in bladder behavior following insertion of the AUS as described above.

Cystourethrography could eventually demonstrate a urethral diverticulum at the site of previous cuff erosion (**Figure 10**).

Endoscopy will disclose any urethral erosion by the cuff (**Figure 11**).

Retrograde perfusion sphincterometry has been reported to diagnose the loss of compressive pressure in the urethral cuff [29]. It is done by infusing fluid from the meatus in a retrograde fashion. If the AUS cuff is functional and the urethral is intact there should be no flow when the pressure equals the AUS balloon pressure. This technique can also be used intraoperatively to detect urethral perforation or to adjust the pressure in the cuff [32]. This seems to be more useful than urethral pressure profile (UPP) [403].

Intraoperative electrical testing, using an ohmmeter [417, 428] has been described to determine the site of fluid leakage from the system. This test can be helpful to avoid the need to change the whole system, and allow replacement of the leaking part only.

## 7. TREATMENT OF COMPLICATIONS

As outlined above, complications directly related to the presence of an artificial sphincter can be divided into categories: incontinence from alteration in bladder function, urethral atrophy, and/or mechanical failure, and infection/erosion. The treatment of each of these complications deserves comment, as no detailed reference can be found in the literature dealing with the treatment of these complications.

### *a) Alterations in bladder function*

De novo (or pre-existing) detrusor overactivity can be treated with parasympatholytics. In a small proportion of patients systemic side effects will prevent the use of these drugs; there might also be some medical contraindications, or the drug may be ineffective. Other options such as bladder augmentation

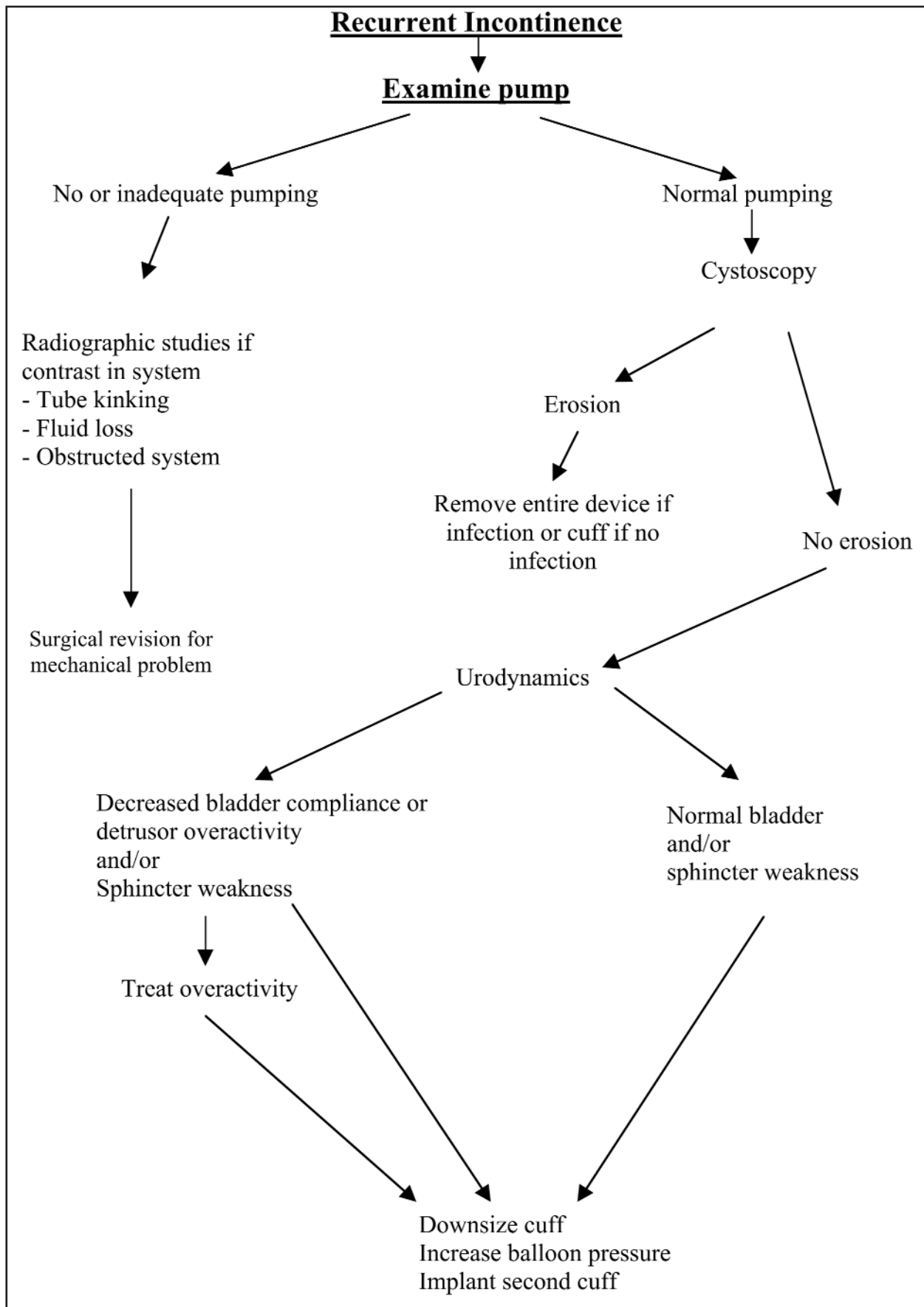
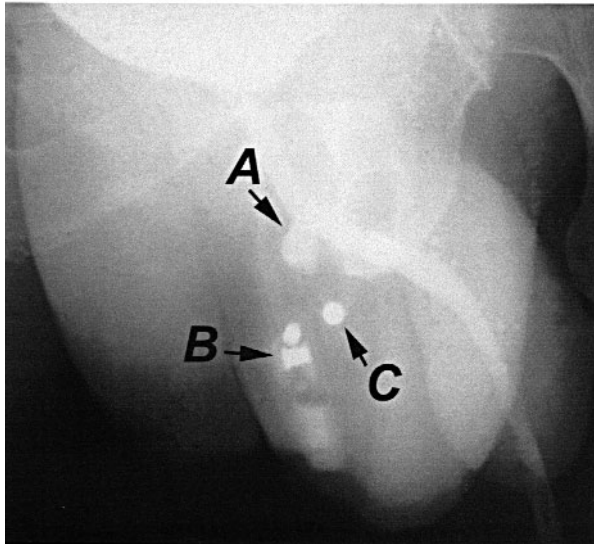
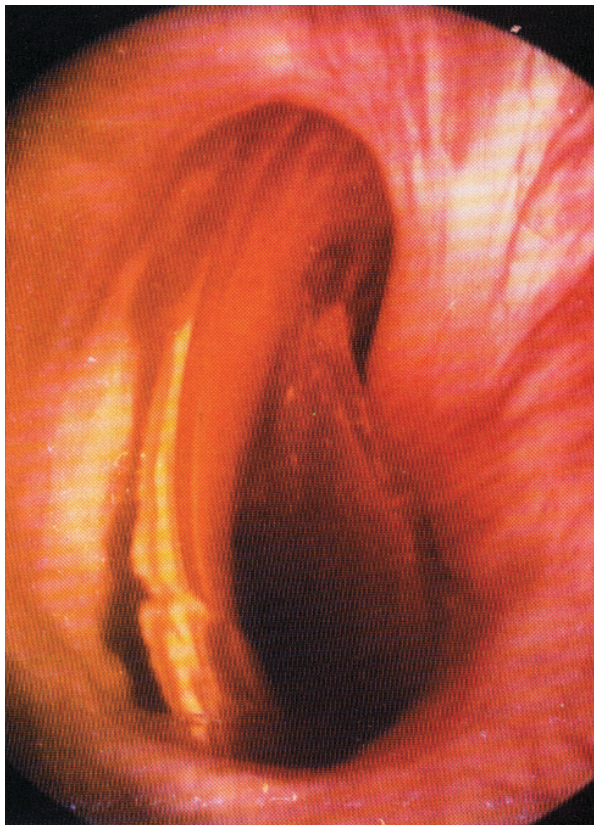


Figure 9. Algorithm for managing incontinence after AUS placement





**Figure 10.** Urethrogram of patient who underwent cuff removal for erosion into the urethra. A. Site of urethral diverticulum B. Tubing plug over tube from pump C. Scrotal pump



**Figure 11** Endoscopic view of AUS cuff erosion into the bulbar urethra. The patient had undergone radiation after radical prostatectomy.

or enterocystoplasty may be considered. To date no report can be found where implantation of an artificial sphincter resulted in the deterioration of the upper urinary tract in a neurologically normal post-prostatectomy patient [124, 408]. It has been reported that enterocystoplasty performed together with the placement of an AUS in the same operative session does not increase the morbidity of the procedure and does not affect the success rate [391]. However, in a recent review of 286 patients Furness et al. [432] demonstrated an infection rate of 14.5% and 6.8% with simultaneous and staged procedures, respectively. No clear urodynamic guidelines exist to select patients who need bladder augmentation in combination with an AUS [409], although small voided volumes with reduced cystometric capacity, poor compliance, or severe detrusor overactivity after failed medical treatment would suggest the need.

#### **b) Atrophy of the urethra**

Several therapeutic options exist to increase cuff pressure around the atrophied urethral wall: changing the balloon reservoir for one generating a higher pressure, downsizing the cuff diameter [12, 117, 433], or increasing the amount of fluid in the system. Another approach consists of placing the cuff inside the corporal tunica albuginea on the dorsal aspect of the urethra (transcorporal). This allows a safer mobilization of the urethra and adds some supplementary bulk of tissue to the circumference of the urethra, possibly decreasing the risk of erosion [132]. It should be mentioned, however, that there is a risk of reduced erectile function with this technique.

The implantation of a double-cuff AMS 800 has become more popular, as a primary procedure in the totally or severely incontinent patient [133, 434], or as a salvage procedure, by adding a second cuff, following a failed previous single cuff [130, 131, 434]. It does not appear that morbidity increases with the double-cuff as compared with the single cuff system [133], and patient satisfaction also seems to be higher [134].

#### **c) Mechanical failure**

As with any device, mechanical failure can be expected with the AMS 800 AUS. The treatment involves surgical replacement of the failed component and reconnecting the system.

#### **d) Infection**

With overt infection the accepted treatment option is removal of the entire device and appropriate antibio-

tics. A second system can be subsequently implanted with equally good results [419]. It has been demonstrated, however, that immediate reimplantation of a new AUS after the removal of an infected, but not eroded, prosthesis can be a valid option with an overall success rate of 87% [435].

#### e) Erosion

In case of urethral erosion by the cuff, the “offending” cuff must be removed. No clear guidelines exist whether removal of the whole system is superior to removal of the cuff alone but it must be assessed for infection. If infection is present the whole device should be removed. Reservoir erosion into the bladder has been described following the removal of an eroded cuff [423]. Furthermore, it is not known whether it is necessary to allow the urethra to heal over a catheter versus surgical repair. The former risks diverticulum formation (**Figure 10**), and the latter may increase the amount of the periurethral fibrosis. This might compromise success of a new cuff. However, the new cuff should be positioned away from the erosion site. In case of the erosion of one of the cuffs of a double system removal of the eroded cuff can successfully convert a double-cuff system into a single cuff system [436].

### 8. CONSENSUS PROTOCOL FOR FOLLOW-UP OF PATIENTS WITH AUS

As complications continue to be seen for years after implantation [437], it is helpful to have a structured follow-up plan. However, no standardized recommendations are available in the literature.

The consensus upon which the members of this subcommittee agreed and which is based on expert opinion are as follows:

1. Perioperative antibiotics are recommended. Gram-negative enteric bacteria and *Staphylococcus epidermidis* are the most frequently encountered microorganisms in infected prostheses [421].
2. Hospital stay should be kept to a minimum.
3. Urethral catheters should be withdrawn within 24-48 hours of surgery and the preoperative continence management continued.
4. In general the sphincter device should not be activated immediately postoperatively. In the initial period scrotal oedema and pain prevent patients from manipulating the pump adequately. When this subsides after 6 to 8 weeks the device can be activated. Earlier activation may also be accep-

table. Irradiated patients may benefit from a longer initial period of deactivation, up to 12 weeks [117]. Nocturnal deactivation should be considered in high-risk patients [116].

5. Patients are reviewed at 3 months after activation to ensure the device is working adequately, and to assess the continence status.
6. Long-term follow-up is different in the neurogenic and non-neurogenic patient. With time, alteration in bladder function may jeopardize renal function in the neurogenic patients. Periodic ultrasound evaluation of the upper urinary tract is essential. If changes occur, urodynamic studies should be done to rule out detrusor overactivity. In non-neurogenic patients, periodic ultrasound may not be necessary.
7. When change in the continence status occurs diagnostic procedures related to sphincter failure (**Figure 9**) should be considered.

**(Level of evidence 3; Grade of recommendation C)**

## XIII. NEW TECHNOLOGY

### ADJUSTABLE CONTINENCE THERAPY – ACT – NEW TECHNOLOGY BEING EVALUATED

The ACT device for male incontinence was introduced in 2000 and consists of silicone balloons connected to a port that can be punctured percutaneously after implantation for readjustment of balloon volume. Using a minimally invasive perineal approach, the balloons are placed underneath the bladder neck bilaterally under fluoroscopic and endoscopic guidance. Elevation and compression of the bladder neck and the membranous urethra is the functional concept of the ACT device. In contrast to most other procedures, the device can be readjusted numerous times after the operation until continence is fully restored. If urinary retention occurs, it can be easily managed by partial balloon deflation. Since bladder neck compression is not circumferential, urethral atrophy due to impaired perfusion, as frequently seen with the artificial sphincter cuff, is very unlikely to occur. Pelvic irradiation heavily increases the risk of balloon migration and/or bladder erosion. Therefore, radiation therapy of the pelvis should be considered as a relative contraindication for implantation of an adjustable continence therapy device. Like sling procedures, the ACT device is neither intellectually nor



manually as demanding as the artificial sphincter. If the ACT implantation fails for any reason, the device can be explanted easily and every other therapeutic option is still possible. Preliminary treatment outcome results show a 75% cured and improved rate in a total of approximately 100 male patients followed for up to one year [438-440]. Further results are anticipated.

## XIV. SUMMARY AND RECOMMENDATIONS

### 1. EVALUATION

Prior to surgery a basic patient evaluation should consist of history and physical examination, urinalysis and postvoid residual urine. A voiding diary is helpful. Pad tests may be useful in certain circumstances. Blood testing (BUN, creatinine, glucose) is recommended if compromised renal function is suspected or if polyuria (in the absence of diuretics) is documented. Additional testing with cystoscopy and appropriate imaging of the urinary tract are also helpful in guiding therapy.

The committee felt that multichannel urodynamics are essential prior to invasive treatment for incontinence. **(Level of evidence 2-4; grades of recommendation A, B, C)**

### 2. INCONTINENCE POST PROSTATECTOMY FOR BPH AND POSTRADICAL PROSTATECTOMY FOR PROSTATE CANCER

After a period of conservative management, which may also be from 6 to 12 months, the artificial sphincter is the preferred treatment for properly selected men who have stress incontinence after radical prostatectomy. Male slings are a proven alternative although long-term data are lacking. Injectable agents are a less effective but an option for some men with mild to moderate incontinence. **(Level of evidence 3; grade of recommendation C)**

### 3. AGE

Age is not a restriction for surgical treatment of urinary incontinence. Cognitive impairment and lack of dexterity may be restrictions for the artificial sphincter and must be determined preoperatively. **(Level of evidence 3-4; grade of recommendation C)**

### 4. INCONTINENCE FOLLOWING OTHER TREATMENTS FOR PROSTATE CANCER

The artificial sphincter is most widely used but radiation may be a risk factor for an increase in complications. Based upon limited data perineal compression (bone anchor) slings are an alternative. Injectable agents have not been successful in this setting. **(Level of evidence 3; grade of recommendation C)**

### 5. INCONTINENCE FOLLOWING PELVIC TRAUMA

The artificial sphincter is most widely reported. Bladder neck reconstruction has also been reported on a limited basis. **(Level of evidence 3; grade of recommendation C)**

### 6. INCONTINENCE IN ADULT EPISPADIAS-EXSTROPHY COMPLEX

Patients should be treated in centres of excellence. A patient-directed approach should be taken. The choices include further bladder neck reconstructive surgery, bladder neck closure, bladder reconstruction or diversion with bowel. The data are insufficient for a specific recommendation. Transition is important between the pediatric and adult urologist. Life-long follow-up is mandatory in terms of continence, voiding efficiency, upper tract status and other urological complications **(Level of evidence 3; Grade of recommendation C)**

### 7. REFRACTORY URGENCY INCONTINENCE AND DETRUSOR OVERACTIVITY

Botulinum toxin-A bladder injections is a minimally invasive treatment with some efficacy. Neuromodulation is a treatment option with success reported in a limited number of male patients. Detrusor myectomy has also been reported to be successful in a small number of male patients. Augmentation cystoplasty is potentially successful in controlling symptoms but may be associated with unacceptable side effects. Urinary diversion is a final option. **(Level of evidence 3; grade of recommendation C)**

### 8. REDUCED CAPACITY BLADDER

Augmentation cystoplasty has been successful in most etiologies apart from radiation. **(Level of evidence 3; grade of recommendation C)**

## 9. URETHROCUTANEOUS FISTULA AND RECTOURETHRAL FISTULA

Etiologic factors causing acquired urethrocutaneous fistulae are demonstrated by clinical, endoscopic and imaging studies. Surgical reconstruction is applied as required. Similar diagnostic maneuvers are applied to rectourethral fistulae. In those that do not close with or without temporary urinary and fecal diversion, surgical reconstruction may be carried out. Most repairs are now carried out after prior fecal diversion. Various techniques are available for closure and can be done in collaboration with colorectal surgeons. **(Level of evidence 3; grade of recommendation C)**

## 10. MANAGEMENT OF AUS COMPLICATIONS

Incontinence may result from alteration in bladder function, urethral atrophy, or mechanical malfunction. Infection and/or erosion of components demand surgical removal of all or part of the prosthesis. A treatment algorithm is presented to aid in management and in follow-up of patients. **(Level of evidence 3; grade of recommendation C)**

## 11. NEW TECHNOLOGIES

Evidence for the ACT balloon is required before specific recommendations can be made.

(Level of evidence C; grade of recommendation D)

## 12. RECOMMENDATIONS FOR FUTURE RESEARCH

- New technologies, bulking agents, sling materials, prosthetic devices should continue to be evaluated
- Clinical trial recommendations
  - Randomized trials (eg. AUS and slings)
  - Standardized workup and outcome measures including QoL
  - Complete reporting of complications
  - Long-term results (>2 years)
  - Standardized reporting of durability

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