Committee 13

Surgical Treatment of Urinary Incontinence in Men

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Surgical Treatment of Urinary Incontinence in Men

S. Herschorn, H. Bruschini, C. Comiter, P. Grise, T. Hanus, R. Kirschner-Hermanns

I. INTRODUCTION

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 and other treatments for prostate cancer.

Basic evaluation of the patient is similar to other areas of incontinence and includes primarily a clinical approach with history, frequency-volume chart or bladder diary, and physical examination. Since most of the surgeries apply to patients with incontinence after other operations or trauma, other investigations such as 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 or improved 75-80% of sufferers. Injection therapy with agents such as collagen has helped 40-50% of men in the short term but fewer in the long term. New sling techniques have shown promising results in studies.

Radical prostatectomy for prostate cancer is performed far more frequently now than 10-15 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 result in most cases with a positive impact on quality of life. Sling procedures are increasingly being reported to have a good outcome. Injectable agents have not shown durable long-term results but newer technologies such as volume-adjustable balloons have shown reasonably favourable early results in a number of reports.

With new data emerging stratification of treatment based on the degree of stress incontinence may become feasible.

Incontinence following radiation therapy, cryosurgery, high-intensity focused ultrasound, 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 pediatric age 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.

1. 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 Third 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.

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. Recommendations for future research are also included.
Recommendations for evaluation prior to surgery have not changed substantially from the last edition in 2005[1]. 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, bulbocavernous reflex[3], urinalysis, and postvoid residual urine. A frequency-volume chart[4], or bladder 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 data in a voiding diary. 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. 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 are recommended in incontinent males prior to surgical therapy.

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

II. EVALUATION PRIOR TO SURGICAL THERAPY

Table 1. Classification of surgically correctable problems

<table>
<thead>
<tr>
<th>SPHINCTER RELATED</th>
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<tbody>
<tr>
<td>Postoperative</td>
</tr>
<tr>
<td>Post-prostatectomy for prostate cancer</td>
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<tr>
<td>Post-prostatectomy for benign disease</td>
</tr>
<tr>
<td>TURP and radiation for prostate cancer</td>
</tr>
<tr>
<td>Post-cystectomy and neobladder for bladder cancer</td>
</tr>
<tr>
<td>Post-traumatic</td>
</tr>
<tr>
<td>After prostatomembranous urethral reconstruction</td>
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<tr>
<td>Pelvic floor trauma</td>
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<tr>
<td>Unresolved pediatric urologic incontinence</td>
</tr>
<tr>
<td>Exstrophy and epispadias</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>BLADDER RELATED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refractory urgency incontinence due to detrusor overactivity</td>
</tr>
<tr>
<td>Small fibrotic bladder</td>
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<tr>
<th>FISTULAE</th>
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</thead>
<tbody>
<tr>
<td>Prostato-rectal (urethrorectal)</td>
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<tr>
<td>Urethrocutaneous</td>
</tr>
</tbody>
</table>

In the opinion of the Committee a thorough urodynamic evaluation to characterize the underlying pathophysiology is useful 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. Peschers et al. 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 a 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]. However, this observation is not consistent [26]. Unfortunately, there is no agreed standardization of the technique 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 during bladder filling. It can be coupled with fluoroscopic imaging, video-urodynamics. It has also been proposed by some that fluoroscopy be replaced by transrectal ultrasound [34, 35]. Ultrasound measurement of bladder wall thickness was proposed as a better predictor of bladder outlet obstruction than uroflowmetry [36] but at present is controversial [37]. Non-invasive pressure-flow urodynamic evaluation based on Doppler ultrasound seems to have potential for diagnosing bladder outlet obstruction [38]. However invasive pressure-flow studies are still the gold standard in the incontinent male to rule out bladder outlet obstruction accompanied by detrusor overactivity [39] which in turn can cause incontinence.

In most recently published studies, urodynamic testing has been done prior to surgery [40-44]. Cystoscopy is frequently done as well [43, 45-49]. However there are some reports that questioned the value of urodynamics studies in predicting outcomes after
surgery. Thiel et al [50] found no evidence that patients with detrusor overactivity, low first sensation filling, decreased compliance or low bladder capacity had worse outcomes after artificial sphincter placement in 86 men. Trigo Rocha et al [51] also found that preoperative urodynamic findings such as detrusor overactivity, impaired detrusor contraction, low valsalva leak pressure, bladder outlet obstruction, and mildly reduced compliance did not lead to a bad outcome after artificial sphincter implantation.

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 a significant problem. Although its rate has lessened [52] 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 lead to an overall increase in the number of patients affected.

Data from large multicenter studies and prostate cancer databases suggest that following RP, 1% to 40% of patients complain of persistent urinary incontinence. The incidence of post prostatectomy incontinence (PPI) depends on the definition of urinary incontinence and the length of follow-up [53-55]. In addition to numerous definitions of incontinence, the tools used to evaluate incontinence vary from validated questionnaires, to interviews from a data manager, to response to the surgeon’s inquiry.

Recent reports of large cohorts use definitions that include “total control/perfect continence”, “occasional leakage but no pad”, and “less than one pad”. Because 1/3 to 1/2 of men who do not wear pads will have occasional leakage of urine, it is important to distinguish among those men who leak enough to require pad use and those who do not, as it has been demonstrated that 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 [56]. In addition, not all men who leak will elect to have further treatment. Most large cohort studies indicate that between 6% and 9% of patients undergo subsequent surgical treatment for PPI following prostate cancer surgery [57-60]. Several large cohort studies are listed in Table 3 [55, 61-74].

2. RISK FACTORS

Reported risk factors for incontinence following radical prostatectomy include patient age at surgery, stage of disease, surgical technique including nerve sparing, preoperative bladder function and urinary continence status, prior radiation therapy, preoperative length of the membranous urethra, prior transurethral resection of the prostate (TURP), and vascular comorbidities. 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. However, previous brachytherapy does predispose to post-TURP incontinence (Section VII in this chapter).

Pre-operative urinary incontinence has been reported as a risk factor for post-operative SUI. While pre-operative lower urinary tract symptoms, including urgency incontinence and “overflow incontinence” may improve with de-obstruction secondary to extirpative surgery [75], pre-operative SUI does not improve following RP. Several recent cohort studies have demonstrated that pre-operative sphincteric insufficiency (demonstrated either the pre-existing clinical sign of SUI or the urodynamic finding of lower maximal urethral closure pressure) predicts post-operative SUI [76, 77]. Pre-operative bladder dysfunction can also contribute to post-operative incontinence. Pre-existing abnormalities of detrusor function may predispose to leakage following surgery, especially in the setting of neurogenic detrusor overactivity due to Parkinson’s disease, dementia or spinal cord injury [78].

Advancing age as a risk factor is supported by several studies [60, 75, 79-83]. Steiner, et al found no
correlation between age and continence status, but only 21 of the 593 patients were 70 years or older [84]. Others have found advancing age and the number of co-morbidities to have a negative impact on the recovering time for continence during the first year after radical prostatectomy [85] although the rate at one and two years did not seem to be significantly affected [86]. Mohamad and colleagues reviewed 16,524 patients who underwent RRP in public hospitals, covering 95% of all procedures in Austria between 1992 and 2003. They found that increasing age was associated with an increased risk of future AUS implantation. In those aged 45-49, 0.5% were bothered enough by PPI to merit AUS placement, while those age 70-74 were five times as likely to undergo AUS placement for PPI. [87] Similarly, Rogers, et al demonstrated that age affected post-operative continence status following laparoscopic RRP. In those < 50 years old, 100% achieved 0-1 pad per day continence at 1 year, which decreased to 91% and 81% for those age 50-59 and > 60 yrs, respectively (p<0.01) [88]. Strasser and colleagues hypothesized that age related sphincteric changes may be responsible for the age-related increase in post-operative SUI, and successfully demonstrated a progressive reduction in sphincter striated muscle cells with age [16].

Most large series have found no correlation between the stage of disease and incontinence rates [80, 81, 89-91] Loeb and colleagues specifically demonstrated excellent continence rates even in high risk (high local stage) patients [92]. However, in certain cases, the stage of disease may affect the surgical technique (i.e. nerve sparing) and incontinence rates may be higher, but this appears to be a reflection on surgical technique and not disease stage [82].

Regarding surgical technique, the many parameters involved in continence may explain difficulties in understanding the benefit of certain technical points. Bladder neck preservation has been reported to improve continence at 3 months [90] no difference was found at 6 and 12 months [93, 94]. Nerve sparing has no significant impact according to Steiner et al. [84] and Lepor and Kaci [66] recently confirmed this. Others did find benefit [76]. In particular, Nandipati and

### Table 3. Continence rates after radical prostatectomy according definition of continence,

<table>
<thead>
<tr>
<th>Author</th>
<th>No. pts.</th>
<th>Mean age (years)</th>
<th>Continence follow-up at 12 months</th>
<th>Type of surgery</th>
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<tbody>
<tr>
<td>Kielb, et al [61]</td>
<td>90</td>
<td>59.6</td>
<td>76%</td>
<td>RRP</td>
</tr>
<tr>
<td>Sebesta, et al [62]</td>
<td>675</td>
<td>&lt;65</td>
<td>43.7%</td>
<td>RRP</td>
</tr>
<tr>
<td>Lepor and Kaci [63]</td>
<td>92</td>
<td>58.7</td>
<td>44.6%</td>
<td>RRP</td>
</tr>
<tr>
<td>Olsson, et al [55]</td>
<td>115</td>
<td>65.2</td>
<td>56.8%</td>
<td>LRP</td>
</tr>
<tr>
<td>Madalinska, et al [64]</td>
<td>107</td>
<td>62.6</td>
<td>33%</td>
<td>RRP</td>
</tr>
<tr>
<td>Deliveliotis, et al [65]</td>
<td>149</td>
<td>66.5</td>
<td>92.6%</td>
<td>RPP</td>
</tr>
<tr>
<td>Harris, et al [66]</td>
<td>508</td>
<td>65.8</td>
<td>96%</td>
<td>RPP</td>
</tr>
<tr>
<td>Maffezzini, et al [67]</td>
<td>300</td>
<td>65.5</td>
<td>88.8%</td>
<td>RRP</td>
</tr>
<tr>
<td>Hofmann, et al [68]</td>
<td>83</td>
<td></td>
<td>74.7%</td>
<td>RRP+/-Rx</td>
</tr>
<tr>
<td>Ruiz-Deya, et al [69]</td>
<td>200</td>
<td>63</td>
<td>93%</td>
<td>RPP</td>
</tr>
<tr>
<td>Augustin, et al [70]</td>
<td>368</td>
<td>63.3</td>
<td>87.5%</td>
<td>RRP</td>
</tr>
<tr>
<td>Anastasidis, et al [73]</td>
<td>70</td>
<td>65</td>
<td></td>
<td>RRP</td>
</tr>
<tr>
<td></td>
<td>230</td>
<td>64</td>
<td></td>
<td>RRP</td>
</tr>
<tr>
<td>Sacco, et al [74]</td>
<td>985</td>
<td>65</td>
<td>83</td>
<td>RRP</td>
</tr>
<tr>
<td>Jacobsen, et al [72]</td>
<td>172</td>
<td>64</td>
<td>87</td>
<td>RRP</td>
</tr>
<tr>
<td></td>
<td>67</td>
<td>61</td>
<td>83</td>
<td>LRP</td>
</tr>
<tr>
<td>Rassweiler, et al [71]</td>
<td>219</td>
<td>65</td>
<td>89.9%</td>
<td>RRP</td>
</tr>
<tr>
<td></td>
<td>219</td>
<td>64</td>
<td>90.3%</td>
<td>LRP</td>
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colleagues reported that in a cohort of 152 patients followed prospectively, bilateral nerve sparing surgery was associated with a shorter time to regain continence as well as improved long-term continence rates compared to non-nerve sparing surgery. They additionally found that increased age was a risk factor for post-prostatectomy incontinence.[95] Burkhard, et al. similarly demonstrated a positive effect of nerve-sparing surgery on post-operative continence. In a prospective cohort study of 536 patients, PPI developed in 1/75 (1.3%), 11/322 (3.4%), and 19/139 (13.7%) with attempted bilateral, attempted unilateral and without attempted nerve sparing, respectively. Attempted nerve sparing was in fact the only statistically significant factor influencing urinary continence after RRP in this cohort. [96]

Within the last decade, laparoscopic and robotic-assisted laparoscopic radical prostatectomy have become standard treatments for men with prostate cancer. At this time the body of available data on post-operative continence is limited, but it would appear that incontinence rates are similar between open and laparoscopic/robotic approaches. Several studies have compared the techniques either prospectively in non-randomized fashion, [72, 73] retrospectively, [97] or via limited meta-analysis [71, 98] and similar continence rates were found. 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 [66, 99, 100].

3. PATHOPHYSIOLOGY

Post-prostatectomy incontinence, like any urinary incontinence, may be caused by bladder dysfunction, sphincter dysfunction or a combination of both. Urodynamic 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 [99, 101]. 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% [102, 103]. 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 [104].

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 [102]. 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 significantly related to time to 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 [105]. Urodynamic studies revealed that a reduced functional urethral length was a predictive parameter of incontinence [76, 106, 107]. Different components of the urethra may also be involved. The urethral intrinsic component responsible for passive continence as well as the extrinsic component responsible for active continence may be involved as has been demonstrated in a urodynamic alpha blockade test [108]. This may explain passive incontinence despite a high voluntary urethral pressure or that measured during an active squeeze by the patient. Post-operative disruption of the innervation of the posterior urethra may also be involved and can affect both motor and sensory functions [109, 110]. 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) [111]. 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 influence 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, but only if such measures are instituted before or immediately after catheter removal [112, 113]. 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 [114]. A randomized study in which randomization occurred 6 weeks after surgery showed no difference in continence at 6 months [115]. On the same note, studies in which physiotherapy was used as a treatment modality for established incontinence have shown more variable results [116-119].

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 [120-127]. 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 [121, 123, 124, 127]. One study reported more favorable results for collagen in treating incontinence after transurethral prostatectomy as opposed to radical prostatectomy (35.2% “social continence” versus 62.5%) [124]. It appears that collagen injection does not adversely affect outcomes of artificial sphincter implantation and does not increase the complication rate [128]. Nor does collagen injection adversely affect the outcome of the bone-anchored male sling (BAMS). [129, 130] The cost efficacy of injections remains to be determined.

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 [131]. They also noted that a urethral closure pressure of at least 30 cmH2O was essential for success. Kylmala et al. prospectively studied 50 patients with mild to moderate SUI (average 48 cc on 1 hour pad test), with 12% achieving short-term continence following 1 injection, and an additional 20%, 18%, and 10% achieving continence with 2, 3, and 4 injections respectively. Follow-up, however, was limited to 3 months [132]. In a randomized trial of AUS versus Macroplastique injection in patients with minimal SUI (the vast majority had SUI following BPH surgery, with greater than 1/3 of the cohort suffering from SUI following RRP), Imamoglu and colleagues demonstrated no difference in success with AUS versus Macroplastique. However, in patients with more severe incontinence, AUS was superior, with minimal improvement following transurethral Macroplastique [47].

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 those of currently available agents. These agents include carbon coated zirconium oxide beads (DuraspHERE®), hyaluronic acid dextranomer (Zuidex®), dimethyl sulfoxide/ethylene vinyl alcohol copolymer (Tegress®, Uryx™), hydrolxapatite spheres in carboxymethylcellulose carrier (Coaptite), and autologous muscle cells, stem cells, and fibroblasts.

In a single institution series of 18 patients followed for an average of 4.2 months, injection of ethylene vinyl alcohol copolymer, (Tegress, C.R. Bard, Inc., Covington, GA) 41.1% of patients achieved at least a 50% improvement, but the complication rate was 58.8%. Accordingly, this compound is no longer available as an injectable agent [133].

Transurethral injection of living muscle stem cells to reconstitute the deficient urethral sphincter has recently been introduced. Mitterberger and colleagues demonstrated a 67% continence rate at an average of 1 year follow-up in a cohort of men suffering from PPI who were treated with transurethral ultrasound guided injections of autologous fibroblasts and myoblasts obtained from skeletal muscle biopsies [134]. An earlier report from the same group demonstrated that men with PPI achieved a 52% dry rate with injection of adult autologous stem cells, which was superior to a similar cohort of men treated with collagen injection [135]. However, it must be pointed out that there was a retraction issued by the editors of The Lancet [136] for a previous article on the treatment of female SUI with autologous cells published by the same group [137]. The project was investigated by the AGES PharmMed, a department of the Austrian Government’s Agency for Health and Food Safety. The editors stated that in their view “the conclusions of the official investigation pinpoint so many irregularities in the conduct of their work that, taken together, the paper should be retracted from the published record.”

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 is based upon the concept of passive external urethral compression, and has recently emerged as a treatment for PPI. The male
sling is actually based on the concept similar to that described by Kaufman and associates in the early 1970’s [138-140]. 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 PPI and patient desire 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. Therefore, most successful sling surgeries rely on a device that is placed under tension, occluding the urethra at rest, and during stress manoeuvres [141-143].

Schaeffer and Stamey described the bulbourethral sling which uses Dacron bolsters placed under the urethra, which are suspended to the anterior rectus fascia by sutures [144]. Data on this procedure are limited to retrospective analyses from the two authors who described the procedure: it has 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 [144]. 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 [145]. They also reported that the bulbourethral sling did not cause significant outlet obstruction [146].

The long-term efficacy of the bulbourethral sling was evaluated in 2005, where 95 patients were followed retrospectively at an average of 4 years post-operatively. With follow-up questionnaires returned by 71 patients, the authors found that in patients who had undergone radiation, had worse outcomes with 14% dry and 43% requiring 1 or 2 or fewer pads daily. Those patients who had not had radiation treatment had a cure rate of 42% and 72% used only 0-2 pads per day for mild leakage [147]. Others have described a bulbourethral sling using a polypropylene mesh graft with or without a porcine dermis backing (presumably to reduce the risk of erosion) [48]. In two small studies of 9 [148] and 16 [48] 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 bulbo-spongious muscle and a 1 cm wide polypropylene sling is placed over this and passed through the retropubic space to emerge from two suprapubic incisions (similar to the tension free vaginal tape procedure in women) [48]. He reported a 69% cure rate at a mean follow up of 14 months. Eight intraoperative bladder perforations healed without complication.

Xu and colleagues described a bulbourethral composite suspension utilizing a suburethral polyester patch plus a narrow polypropylene tape passed from a perineal incision to a suprapubic incision. At an average of 28 months, 22 (85%) of 26 patients were successfully treated [149].

The most common method of sling fixation involves use of bone anchors. The bone anchored male sling (BAMS) has increased in popularity, as bone anchor fixation obviates the need for any suprapubic incision for suture passage and fixation. Since 2001, reports of the BAMS have become more prevalent in the literature. In 2001, Madjar, et al reported on 14 patients with post RP incontinence that underwent the procedure with a synthetic or cadaveric fascial sling [150]. 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 [129]. In a 2005 update, the same author reported that with a median of 48 months follow-up, 65% of patients remained pad free and 15% required 1 pad per day [151]. Urodynamic follow up in 22 men, revealed that the sling had no significant effects on voiding function and no man was obstructed postoperatively [152]. Onur and colleagues reported on 46 men with a mean follow-up of 17 months (6-26) [153]. 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. A 24-month update from that group revealed a patient satisfaction rate of 70% and a 74% improvement in leakage at a median of 24 months [154].

Several new slings have been introduced, with a common objective of overcoming the potential problem of overcorrection or undercorrection of continence. Transobturator slings have been introduced, [44, 155, 156] which rely more on rotation of the dorsal surface of the proximal bulbous urethra and indirect support of the sphincteric urethra, rather than direct compression of the urethral lumen [157]. However, small numbers of patients, with limited follow-up do not allow for adequate assessment of this new technique enjoying early popularity.

In an effort to overcome the problem of undercorrection, two “adjustable” slings have been introduced — the readjustable sling procedure (REMEEX), [158], and the “Argus” [159] In 48 patients reported in a Phase III multicenter trial of the Argus...
sling, a 73% continence rate and additional 10% improvement rate was realized at an average of 7.5 months. Erosion and infection necessitated sling removal in 10% of patients. Adjustments were indicated for persistent incontinence as well as for urine retention. In a prospective multicenter Phase II trial of the Male Remex System (MRS) adjustable sling, 51 patients were followed for an average of 32 months (range: 16-50). With 90% of patients requiring at least 2 adjustments, a continence rate of 64.7% was achieved, with an additional 19.6% realizing improvement over baseline [160].

Sling results are shown in Table 4 [40, 41, 48, 144, 147-154, 158-165].

1. Complications

Due to the small size of most reported cohort series of male sling patients, and due to the limited body of literature on the subject, the precise complication rate is [163] not known. However, reports from the largest cohorts of patients reveal an infection rate ranging from 0-6%, and a urethral erosion rate of 0-2% [41, 151, 163]. Bothersome scrotal pain or numbness affects 16%-72% of patients post-operatively, but has been reported to resolve in all patients by 3 months [151, 165]. Reported rates of recurrent incontinence following sling surgery, amenable to revision surgery, are low (<5%) [41, 151, 154]. But the small sizes of the cohorts, and the limited follow-up of < 5 years prevent meaningful comparisons to the AUS at this time. Urinary retention is uncommon with male sling surgery, and may be avoided by excluding those patients with detrusor underactivity on pre-operative urodynamics [165, 166].

2. Predictors of Success

Several cohort studies have demonstrated that prior radiation therapy is associated with diminished efficacy of the male sling, probably due to urethral fibrosis and inadequate urethral coaptation [147, 153, 165]. In addition, the use of organic (resorbable) material is less efficacious than synthetic (permanent) sling material [153, 163, 165]. The treatment of male ISD with a suburethral sling requires tension which can only be maintained with the use of synthetic material. Pre-treatment severity of incontinence measured by the degree of leakage also appears to influence sling results. Several reports indicate that those with more severe leakage do not achieve similar continence rates when compared to those with milder leakage [153, 163, 165]. Fischer and colleagues were able to quantify, in prospective fashion, that leakage greater than 423 gm on pre-operative pad weight predicted an inferior outcome, compared to those men with less leakage on pre-operative pad weight test [41]. In their report, 62 patients with SUI were followed prospectively. All patients were rigorously evaluated with 24-hour pad test, urodynamics and validated incontinence questionnaires. Success was determined by the Patient Global Impression of Improvement. Overall, 36/62 (58%) of surgeries were successful at a mean follow-up of 15 months. The only preoperative predictive factor was 24-hour pad weight. If pad weight was less than 423 gm, there was a 6-fold greater success rate compared to those with a pre-operative pad weight of greater than 423 gm.

Finally, previous AUS placement and explantation predict sling failure [152, 163]. However, it is not clear if this is directly due to the urethral fibrosis and poor urethral coaptability, and/or if those patients simply suffer from more severe incontinence, which interferes with successful sling surgery.

CONCLUSION

In the intermediate term, the male sling appears to perform reasonably well. In the UK as well, the National Institute for Health and Clinical Excellence (NICE) has stated that current evidence on the safety and efficacy of slings appears adequate to support their clinical use [167].

The best candidates appear to be those with lower and moderate degrees of incontinence, who have not had previous radiation. While reported revision rates due to recurrent incontinence are quite low, longer follow-up is obviously needed before definitive comparisons to the AUS can be made. Nevertheless, in men with adequate detrusor contractility and mild to moderate degrees of SUI, or for patients demanding a less invasive procedure or non-mechanical device, a sling procedure is a reasonable alternative to artificial sphincter, although longer term outcome is unknown. (Level of evidence 3; Grade of recommendation C)

3. Adjustable Balloons

The adjustable balloon procedure is based upon the concept of passive compression of the urethra utilizing two balloons located on either side of the urethra. Balloons may be progressively inflated until there is optimal coaptation, thereby achieving continence. The biomaterial name ACT™ (Adjustable Continence Therapy) was originally conceived and developed for female stress urinary incontinence, and subsequently was applied to male incontinence. The proACT™ device was developed and reported in 2000 [168].

The device consists of a silicone elastomer balloon attached to an injectable titanium port via a silicone tube. A balloon is implanted on either side of the urethra, either under the bladder neck for post-radical prostatectomy incontinence, or under the veru montanum for post-TURP-incontinence. The ports are located subcutaneously in the scrotum, allowing simple access for percutaneous adjustment of the balloon volume. The implantation is performed under general or spinal anesthesia through a short perineal...
<table>
<thead>
<tr>
<th>Authors</th>
<th>No. Patients</th>
<th>Mean Follow-up (months)</th>
<th>Sling type</th>
<th>Cured (%)</th>
<th>Improved (%)</th>
<th>Failed (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thüroff [161]</td>
<td>22</td>
<td>10.3</td>
<td>Fascia sling with suprapubic and perineal</td>
<td>63.6</td>
<td>9</td>
<td>27.3</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>approaches</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Madjar, et al[150]</td>
<td>16</td>
<td>12</td>
<td>Synthetic or organic</td>
<td>86</td>
<td>14</td>
<td>0</td>
</tr>
<tr>
<td>Dikranian et al[40]</td>
<td>36</td>
<td>12</td>
<td>Organic</td>
<td>56</td>
<td>87</td>
<td>31</td>
</tr>
<tr>
<td></td>
<td>20</td>
<td>12</td>
<td>Synthetic</td>
<td>13</td>
<td>13</td>
<td>0</td>
</tr>
<tr>
<td>Ullrich &amp; Comiter [152]</td>
<td>36</td>
<td>25</td>
<td>Perineal (Invance®)</td>
<td>67</td>
<td>25</td>
<td>8</td>
</tr>
<tr>
<td>Onur et al [153]</td>
<td>46</td>
<td>18</td>
<td>Synthetic or organic</td>
<td>41</td>
<td>35</td>
<td>24</td>
</tr>
<tr>
<td>John [48]</td>
<td>16</td>
<td>14</td>
<td>Polypropylene suspended suprapublicly plus</td>
<td>69</td>
<td>6</td>
<td>25</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>porcine skin collagen</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stern et al[147]</td>
<td>75</td>
<td>48</td>
<td>Bulbourethral suspension</td>
<td>36</td>
<td>32</td>
<td>32</td>
</tr>
<tr>
<td>Rajpurkar et al [154]</td>
<td>46</td>
<td>24</td>
<td>Synthetic or organic</td>
<td>37</td>
<td>37</td>
<td>26</td>
</tr>
<tr>
<td>Comiter [151]</td>
<td>48</td>
<td>48</td>
<td>Synthetic</td>
<td>65</td>
<td>20</td>
<td>15</td>
</tr>
<tr>
<td>Castle et al [163]</td>
<td>42</td>
<td>18</td>
<td>Synthetic</td>
<td>16</td>
<td>24</td>
<td>60</td>
</tr>
<tr>
<td>Migliari et al. [148]</td>
<td>9</td>
<td>14</td>
<td>Polypropylene needle suspension</td>
<td>55.6</td>
<td>22.2</td>
<td>22.2</td>
</tr>
<tr>
<td>Cespedes &amp; Jacoby [162]</td>
<td>9</td>
<td>13</td>
<td>Perineal (Invance®)</td>
<td>66.7</td>
<td>11.1</td>
<td>22.2</td>
</tr>
<tr>
<td>Schaeffer et al. [144]</td>
<td>64</td>
<td>18</td>
<td>Vascular graft bolsters with needle suspension</td>
<td>56</td>
<td>8</td>
<td>36</td>
</tr>
<tr>
<td>Gallagger et al [164]</td>
<td>24</td>
<td>15</td>
<td>Synthetic</td>
<td>38</td>
<td>37</td>
<td>25</td>
</tr>
<tr>
<td>Sousa-Escandon et al. [158]</td>
<td>6</td>
<td>18</td>
<td>Readjustable synthetic suprapubic and perineal</td>
<td>83.3</td>
<td>16.7</td>
<td>-</td>
</tr>
<tr>
<td>Moreno-Sierra et al. [159]</td>
<td>48</td>
<td>7.5</td>
<td>Argus-adjustable</td>
<td>73</td>
<td>10</td>
<td>17</td>
</tr>
<tr>
<td>Romano et al.[160]</td>
<td>51</td>
<td>32</td>
<td>REMEEX- adjustable</td>
<td>64.7</td>
<td>19.6</td>
<td>15.7</td>
</tr>
<tr>
<td>Fischer et al.[41]</td>
<td>62</td>
<td>15</td>
<td>Perineal (Invance®)</td>
<td>34</td>
<td>24</td>
<td>42</td>
</tr>
<tr>
<td>Xu et al. [149]</td>
<td>26</td>
<td>28.3</td>
<td>Bulbourethral composite suspension</td>
<td>73</td>
<td>19</td>
<td>8</td>
</tr>
<tr>
<td>Giberti et al[165]</td>
<td>36</td>
<td>41</td>
<td>Synthetic or organic</td>
<td>62</td>
<td>8</td>
<td>30</td>
</tr>
</tbody>
</table>
incision. A trocar covered with a U-shaped sheath is inserted up to the site of implantation, and then the balloon is pushed along inside the sheath. Fluoroscopic and urethroscopic guidance are used for the procedure. Transrectal ultrasound guided implantation [169] is a possible option. An isotonic medium with sterile water and contrast medium is prepared to fill the balloons with 2 ml during the initial procedure. Then, after a period of time, approximately one month, the balloons are refilled with 1 ml of this solution at each period (maximum filling is 8 ml) until continence is achieved. The adjustment of the filling are volume limited and are carried out step by step in order to obtain a pseudo-capsule surrounding the balloons and therefore to minimize the risk of urethral erosion or migration. Results from 6 prospective studies [43, 46, 170-173] reported are shown in Table 5. Of 170 patients reported by Hubner [170] and Lebret [46], one-third became pad free. In other studies 70% of patients utilized 0-1 pads daily [46, 170-172]. Mean procedure time of 35 minutes was reported. Along with this improvement in pad use, there were parallel improvements in I-Qol quality of life score [46, 170, 171]. Based upon these trials, the mean number of post-operative adjustments of the balloon was 3 to 5, with some patients requiring 6 to 8 refillings.

4. COMPLICATIONS

The most common peri-operative complications are urethral or bladder perforation, necessitating termination of the implant on the perforated side. However, contralateral implantation was not adversely affected, and repeat ipsilateral implantation was invariably achieved after healing of the urethral or bladder wall. Lebret et al. [46] reported a perforation rate of 10% and Hubner [43] reported a rate of 18% early in their series, but a lower urethral perforation rate in the most recent cases – illustrating a relatively short learning curve for optimal balloon placement near the urethral/bladder wall. Temporary urinary retention from presumed obstruction was reported at 5% [43]. Voiding was restored by removing fluid from the balloon.

Device explantation related to balloon failure, infection, erosion, or migration. The explantation rate ranged from 12 to 58% [43, 46, 170-173], but decreased with experience [43]. Device removal is straight-forward, as a deflated balloon can be explanted transperineally. The only reported risk factor for failure and complications was prior external beam radiotherapy [46]. Kocjancic et al. [173] demonstrated a continence rate of 67% in non-radiated patients compared to 36% in radiated patients.

CONCLUSION

The proACT™ balloon technique appears to be a feasible procedure to improve the continence in short and median term, with better results occurring with more operator experience. Similar to the male sling procedure, appropriate candidates include those with mild to moderate leakage due to intrinsic sphincter deficiency, and no previous radiation. The benefit of an adjustable system should be weighed against the need for multiple sessions of refilling the balloon, and with reported rate of peri-operative and post-operative complications. Longer follow-up is needed before definitive comparison to male sling or artificial sphincter can be made. No recommendation is possible due to variable data on complication rates (12-58%). (Level 3, Grade D).

### Table 5. Results and complications of six prospective series of Adjustable Balloons (proACT) in post-prostatectomy urinary incontinence

<table>
<thead>
<tr>
<th>Authors</th>
<th>Number of patients</th>
<th>Follow-up (mo)</th>
<th>Number of adjustments (balloon refilling)</th>
<th>Postoperative Complications with explantation (uni or bilateral)</th>
<th>Continence 0 or 1 pad/day</th>
<th>Complete Continence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hubner [170]</td>
<td>117</td>
<td>13 (3-54)</td>
<td>3 (1-15)</td>
<td>46 %</td>
<td>68 % (46/63)</td>
<td>35 % (22/63)</td>
</tr>
<tr>
<td>Trigo-Rocha [171]</td>
<td>23</td>
<td>22 (6-48)</td>
<td>5 (1-6)</td>
<td>17 %</td>
<td>65 % (15:23)</td>
<td></td>
</tr>
<tr>
<td>Hubner [43]</td>
<td>50 versus 64</td>
<td>22 vs 23</td>
<td>5 vs 4</td>
<td>58 % vs 24 %</td>
<td>52% vs 60 %</td>
<td></td>
</tr>
<tr>
<td>Cansino Alcaide [172]</td>
<td>69</td>
<td>22 (3-48)</td>
<td>2</td>
<td>12 %</td>
<td>70 %</td>
<td>14 %</td>
</tr>
<tr>
<td>Kocjancic [173]</td>
<td>64</td>
<td>20 (12-62)</td>
<td>3 (0-8)</td>
<td>17 %</td>
<td>67 %</td>
<td></td>
</tr>
<tr>
<td>Lebret [46]</td>
<td>62</td>
<td>6</td>
<td>4</td>
<td>31 %</td>
<td>71 %</td>
<td>30 %</td>
</tr>
</tbody>
</table>

(D level 3, Grade D).
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) potentially gives 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 [174, 175]. However, these studies were conducted before male slings and 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 90% [176, 177], as shown in Table 6 [51, 176, 178-187]. Just as with reported rates of incontinence following prostate cancer surgery depend on the definition of incontinence, continence rates with the AUS can vary with the definition of continence, the method of evaluation, and the length of follow-up. The lowest rates are from patient administered questionnaires when pad free rates range from 10-72% [179, 188-192]. Nevertheless, high satisfaction rates of 87% to 90% are consistently reported, even without total continence [180, 184, 188].

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 8-45% and 7-17% [192]. In a large cohort reported by Lai and colleagues [187], non-mechanical failure has decreased from 17% to 9% and mechanical failure decreased from 21% to 8% following introduction of the narrow back cuff and mean time to reoperation was 26.2 months (mean 2-68 months). With a Kaplan-Meier analysis, the overall 5 year expected product survival was 75%. Only 6% of devices failed mechanically, at an average of 68.1 months, with 75% of patients requiring no revisions at 5 years. Actuarial freedom from revision at 5 years was estimated at 50%-75%.

The long term efficacy of the AUS was demonstrated by Fulford et al who reported that at 10-15 year followup, [193] 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 [194, 195] or transcorporal cuff placement [196]. 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 may be compromised. Some have advocated tandem cuffs not only as a salvage procedure, but also as a primary procedure for men with severe incontinence [197, 198]. However, O’Connor et al. recently reported no difference in continence outcome and a higher revision rate in patients undergoing double-cuff implant versus single-cuff after longer follow up [199].

<table>
<thead>
<tr>
<th>Author</th>
<th>No. pts.</th>
<th>Follow-up (yrs.)</th>
<th>0-1 pad/day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Montague [178]</td>
<td>66</td>
<td>3.2</td>
<td>75%</td>
</tr>
<tr>
<td>Perez and Webster [176]</td>
<td>49</td>
<td>3.7</td>
<td>85%</td>
</tr>
<tr>
<td>Martins and Boyd [179]</td>
<td>28</td>
<td>2</td>
<td>85%</td>
</tr>
<tr>
<td>Fleshner and Herschorn [180]</td>
<td>30</td>
<td>3</td>
<td>87%</td>
</tr>
<tr>
<td>Mottet, et al [181]</td>
<td>96</td>
<td>1</td>
<td>86%</td>
</tr>
<tr>
<td>Madjar, et al [182]</td>
<td>71</td>
<td>7.7</td>
<td>59%</td>
</tr>
<tr>
<td>Klijn, et al [183]</td>
<td>27</td>
<td>3</td>
<td>81%</td>
</tr>
<tr>
<td>Haab, et al [184]</td>
<td>36</td>
<td>7.2</td>
<td>80%</td>
</tr>
<tr>
<td>Trigo Rocha, et al [51]</td>
<td>40</td>
<td>4.5</td>
<td>90%</td>
</tr>
<tr>
<td>Kim, et al. [186]</td>
<td>124</td>
<td>6.8</td>
<td>82%</td>
</tr>
<tr>
<td>Lai, et al. [187]</td>
<td>218</td>
<td>3.1</td>
<td>69%</td>
</tr>
<tr>
<td>Goldwasser [185]</td>
<td>42</td>
<td>1.2</td>
<td>82%</td>
</tr>
</tbody>
</table>
An increased revision rate has been reported for patients who received pelvic radiation [179, 200] but was not found in a recent series [177]. The results for continence for radiated patients are variable with some studies showing lower success rates [176, 200] while others do not [191]. It has been recommended that such patients have a lower pressure reservoir and/or longer period of deactivation time [179].

CONCLUSION

The AUS remains the gold standard for the treatment of PPI secondary to sphincteric insufficiency in patients with severe incontinence, and in those who have had external beam radiation treatment. It has the largest body of literature reporting long-term success. The long term success rates and high patient satisfaction seem to outweigh the need for periodic revisions in some patients. Intermediate term data with the male sling demonstrates that the sling is an alternative to the AUS in patients with mild-moderate SUI, provided that those patients have not failed previous AUS surgery, have not had radiation treatment, and have normal bladder contractility. Overall, the AUS remains the reference standard to which all other treatments must be compared. (Level of evidence 2; Grade of recommendation B)

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. In a prospective cohort study of men undergoing RRP, Lepor and Kac [63] demonstrated continued recovery of continence up to 24 months post-operatively, from 80.6% at 3 months to 95.2% at 12 months, plateauing at 98.5% at 24 months. Other cohort studies have demonstrated a plateau in continence rates at 12 months [201, 202]. Since continence may improve up to 12 months post-operatively, and possibly even until 24 months, it is generally recommended that behavioral/conservative management be utilized during the first year after prostate cancer surgery.

There have been some studies evaluating the effect of early interventional treatment for incontinence. Schneider and colleagues [203] demonstrated a beneficial effect on the earlier return to continence with early injection of periurethral bulking agent. Results were better in the subgroup of 34 patients that were injected early (mean 23 days post-operatively) compared to 10 patients treated at a mean of 26 months post-operatively. It could not be demonstrated, however, that long term continence is improved by early injection of bulking agent. Similarly, Jones and colleagues [204] demonstrated in a comparative cohort study of RRP patients treated either with or without a simultaneous suburethral sling, that sling placement at the time of RRP resulted in an earlier return to continence. There was no difference after 24 months. (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 [205]. 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, 2nd, and 3rd International Consultations on Incontinence [1, 206, 207]. 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, TUIP and HoLEP is low: 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 [206]. In a retrospective chart review from Wendt-Nordahl and colleagues [208], the incidence of incontinence following TURP was reported to have decrease over 17 years, from 3.3% in 399 patients operated on between 1987 and 1997, compared to 1.3% in 550 patients operated on from 1997-2004. Whether this statistically significant (p< 0.05) difference was due to improvement in surgical technique or patient characteristics is not clear, however both the earlier and later incontinence rates are consistent with those in the AHCPR and AUA guidelines reports.
In 2003, the AUA published guidelines for the management of "benign prostatic hyperplasia" [209]. The estimated frequency of incontinence following TURP was 3% (from 19 trials that included > 5000 patients). However, the Veterans Affairs Cooperative Study, reported an incontinence rate of only 1% in TURP patients, which was not different from the watchful waiting arm [210]. The AUA conducted meta-analysis of RCTs comparing TURP with TUIP or transurethral electrovaporization did not reveal any statistically significant differences in incontinence rates [209, 211-214].

Over the past decade, transurethral holmium laser enucleation of the prostate (HoLEP) has become a standard treatment for BPO. Review of RCTs by the AUA as well as a meta-analysis of RCTs comparing TURP with HoLEP did not reveal any significant differences in incontinence rates [209, 215-221].

In summary, the incidence of urinary incontinence after open surgery, transurethral resection of the prostate, transurethral incision of the prostate, and holmium laser enucleation of the prostate is low, and does not differ significantly among the various techniques.

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 the timing of 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, 2nd, and 3rd International Consultations on Incontinence [1, 206, 207]. Candidates for treatment with the artificial urinary sphincter (AUS) are patients with incontinence due to intrinsic sphincter deficiency that have normal bladder compliance [222]. 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 bulb urethra via a perineal route or transverse scrotal routes [223] or around the bladder neck [1, 206, 207]. 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 include both post-prostatectomy incontinence for benign and malignant disease [206]. In summary, the AUS is a successful surgical treatment option for post-prostatectomy incontinence. It is the most commonly performed surgery for post-prostatectomy incontinence, with the longest follow-up and therefore longest record of success. Level of evidence 2; Grade of recommendation B)

b) Injectable agents

Most series include post-prostatectomy incontinence after treatment for benign and malignant disease, with the majority after prostate cancer surgery. For collagen, "success rates" range from 36-69%, with 4-20% of patients reporting being dry [120-127]. Study results are inconsistent with both TURP [224] and radical prostatectomy [225] showing better outcomes.

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 initial improvements with success rates of 40%, 71%, 33%, and 26% at 1, 3, 6, and 12 months respectively [131]. As mentioned previously in the section on post-radical prostatectomy incontinence Kylmala et al. prospectively studied 50 patients with mild to moderate SUI (average 48 cc on 1 hour pad test), with 12% achieving continence following 1 injection, and an additional 20%, 18%, and 10% achieving continence with 2, 3, and 4 injections respectively [132]. Follow-up, however, was only 3 months. In a randomized trial of AUS versus Macroplastique injection in patients with minimal SUI (the vast majority had SUI following BPO surgery, with less than 1/3 of the cohort suffering from SUI following RP), Imamoglu and colleagues demonstrated no difference in success with AUS versus Macroplastique. However, in patients with more severe incontinence, AUS was superior, with minimal improvement following transurethral Macroplastique [47]. There has also been some initial work with sphincteric injections of muscle stem cells [134, 135].

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. Although bulking therapy may be slightly more efficacious in treating SUI following TURP compared to SUI following prostate cancer surgery, bulking is of limited value in those men with all but minimal SUI. (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 [226]. Rectus fascia, as described by Frangenheim, has distinct advantages over alloplastic materials with respect to erosion and infection risks. Allograft off-the-shelf-materials like lyophilized fascia lata have a higher infection risk than does autologous fascia,
whereas the use of synthetic materials like polypropylene mesh or polytetrafluoroethylene slings are associated with a higher incidence of urethral erosion [227]. 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 [161]. This mode of action favours sling procedures as a treatment option for intrinsic sphincter deficiency.

However, the sling tension needed for restoration of continence has not been standardized, with tensioning techniques ranging from perfusion sphincterometry, to a cough test, to visual approximation, [153, 228] and therefore the success of the procedure probably depends heavily on the surgeon’s experience and the degree of sphincteric incompetence. Overcorrection with consequent urinary retention (especially in the setting of detrusor underactivity) and undercorrection with persistent or recurrent incontinence are certainly possible, which may adversely affect continence, bladder emptying, and patient satisfaction. Published success rates are shown in Table 4 [40, 41, 48, 144, 147-154, 158-165].

Several new slings have been introduced, with a common objective of overcoming the potential problem of overcorrection or undercorrection of continence. Transobturator slings [44, 155, 156] rely more on rotation of the dorsal surface of the proximal bulbous urethra and indirect support of the sphincteric urethra, rather than direct compression on the urethral lumen [157]. However, small numbers of patients, with limited follow-up do not allow for adequate assessment of this new technique which is enjoying early popularity.

In an effort to overcome the problem of undercorrection, two “adjustable” slings have been introduced — the readjustable sling procedure (REMEEX), [158], and the “Argus” [159]. In 48 patients reported in a Phase III multicenter trial of the Argus sling, a 73% continence rate and additional 10% improvement rate was realized at an average of 7.5 months. Erosion and infection necessitated sling removal in 10% of patients. Adjustments were indicated for persistent incontinence as well as for urinary retention. In a prospective multicenter Phase II trial of the Male ReMex System (MRS) adjustable sling [160], 51 patients were followed for an average of 32 months (range: 16-50). With 90% of patients requiring at least 2 adjustments, a continence rate of 64.7% was achieved, with an additional 19.6% realizing improvement over baseline.

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 reduced infection risk more aged patients are candidates for surgical treatment. Although every surgeon should be aware of those special risks in elderly patients which might require special perioperative care, even in the very old well planned surgical procedures can be safe, and are justifiable, if it helps to improve continence and besides benefiting general health status leads to a better quality of life for the individual. Many studies have documented that the frequency of peri-operative complications increases with age [229]. This finding is not surprising given that the prevalence of significant co-morbid conditions is increased in the elderly [230]. It is however unclear whether the increased frequency of complications can be attributed to these co-morbid conditions or whether advanced age itself is an independent risk factor [231].

PubMed and Medline searches were conducted in May 2008 covering the time frame from 01.01.2004 to the present. The terms ‘surgery, male and urinary incontinence’ were used and the search was limited to English articles to update the previous comprehensive literature search done for the third edition of the ICI.

Data available are still sparse, since the search did not differentiate between fit and frail elderly. Since the latter are defined as patients with continuous severe impairment and/or co-morbidity, 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 came to the opposite conclusion [232]. Advancing age as a risk factor is supported by a number of studies [60, 79-83]. Steiner, et al [84] found no correlation between age and continence status, but only 21 of the 593 patients were 70 years or older. However, Mohamad and colleagues reviewed 16,524 patients who underwent RP in public hospitals in Austria. They found that increasing age was associated with an increased risk of peri-operative complications [87]. Similarly, Rogers, et al demonstrated that age affected post-operative continence status following laparoscopic RP [88]. As mentioned above, Strasser and colleagues hypo-
the nervous system or the anatomical location of the clitoris.
Pre-radiotherapy transurethral prostatectomy may be a risk factor for incontinence. Jonler et al. [250] reported an incontinence rate of 11% with pretreatment TURP. Green et al. [251] and Lee et al. [252] also reported a higher risk of incontinence with pretreatment TURP versus those without with 5.4% and 2% respectively. There are no series reported on the treatment of patients who only have incontinence after EBRT.

Salvage or adjuvant radiotherapy is frequently given after radical prostatectomy and the impact on continence is controversial. Petrovich et al. [253] reported no difference in incontinence in 2 cohorts of patients, one with and one without adjuvant radiation. In a follow-up study the same group reported no late toxicity [254]. Fontaine et al. also reported no change in continence status in 16 of 17 men after salvage radiation [255]. However, Petroski et al. reported that postoperative radiotherapy worsened continence in 26% of 129 patients followed for a median of 5 years [256]. On the other hand salvage radical prostatectomy following external beam radiotherapy has been generally reported to have a high incidence of urinary incontinence [257-259] possibly because of radiation induced fibrosis of the external sphincter [258].

**SURGICAL TREATMENT**

Results of surgical treatment of incontinence in this setting are based on retrospective clinical series. In the past the most commonly published treatment modality was the artificial urinary sphincter as therapy for sphincter damage. As discussed and referenced in the following paragraphs, the series published contain both patients who had and had not received radiotherapy and collagen injections have also been reported in case series.

There has been a higher reported revision rate for the artificial sphincter following radiotherapy (Table 7 [176, 177, 179, 187, 190, 200, 260, 261]) compared to low risk patients, 38% versus 22%. Although recent reports dispute the higher rate [177, 187]. However, generally 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 [179]. Radiation may also induce detrusor overactivity or poor compliance leading to urgency incontinence. Recurrence of bladder neck contracture may be more common [187]. Radiation was also identified as a co-morbidity associated with erosion [262]. However, good results are reported, and it is generally recommended that the cuff be inserted outside the radiated field [263].

Collagen injection has also been reported for incontinence after radical prostatectomy and adjuvant radiation [122, 126, 224, 264-266] or after salvage radical prostatectomy following radiotherapy [129,267]. Continence results are poorer compared to those without radiation [225]. Very few patients have been reported on with the use of Macro-plastique following radical prostatectomy and adjuvant radiotherapy.

The male perineal bone-anchored sling has been reported in patients following adjuvant RT. In Comiter’s group with the perineal compression sling 3/21 with radiation had no adverse sequelae [129] Similarly in the series of Onur et al. radiation did not cause a worse outcome [153]. 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) [144]. 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.

**Table 7. The artificial sphincter for incontinence after radiotherapy**

<table>
<thead>
<tr>
<th>Study</th>
<th>Number of patients</th>
<th>Revision rate after radiotherapy</th>
<th>Continence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Martins and Boyd [179]</td>
<td>34/81</td>
<td>38% (for whole group)</td>
<td>88%</td>
</tr>
<tr>
<td>Wang and Hadley [260]</td>
<td>16</td>
<td>25% (Infection and Erosion - 12.5%)</td>
<td>87%</td>
</tr>
<tr>
<td>Perez and Webster [176]</td>
<td>11/75</td>
<td>55%</td>
<td>63%</td>
</tr>
<tr>
<td>Gundian et al. [261]</td>
<td>15/56</td>
<td>22%</td>
<td>90%</td>
</tr>
<tr>
<td>Elliott and Barrett [190]</td>
<td>46/313</td>
<td>22%</td>
<td>-</td>
</tr>
<tr>
<td>Manunta et al. [200]</td>
<td>15/72</td>
<td>53% (Infection and Erosion – 20%)</td>
<td>73%</td>
</tr>
<tr>
<td>Gomha and Boone [177]</td>
<td>28/86</td>
<td>25% (Similar to a non-Radiated control group)</td>
<td>64%</td>
</tr>
<tr>
<td>Lai et al. [187]</td>
<td>60/176</td>
<td>20% versus 32% for non-radiated group</td>
<td>69%</td>
</tr>
</tbody>
</table>
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 OF THE PROSTATE

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 given in Table 8 [268-279] and was previously related to the treatment of post-brachytherapy retention of urine. Numerous series have reported retention to be associated with larger initial prostate volumes [280]. In a systematic review of brachytherapy series, Crook et al. [277] 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 [274] 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 when required has included the artificial sphincter [275]. High dose brachytherapy that is administered over a short period of time may have reduced toxicity [281]. Urethrectal fistula is another complication that has been reported in 1.8% of patients in a large U.S. medicare retrospective review [275]. Salvage brachytherapy leads to a higher rate of urinary tract complications [259].

2. CRYOSURGICAL ABLATION OF THE PROSTATE

Cryosurgical ablation of the prostate is used for clinically localized prostate cancer either as primary treatment or after unsuccessful external beam radiation therapy. The frequency of the main lower urinary tract complications are listed in Table 9 [282-294]. The artificial sphincter has been mentioned as one of the treatments for incontinence [293] Cryotherapy is an adverse factor for collagen injections. Urethrectal 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 [295].

3. HIGH-INTENSITY FOCUSED ULTRASOUND (HIFU)

Transrectal high-intensity focused ultrasound is emerging as another minimally invasive treatment for prostate cancer. HIFU destroys prostate cells by

<table>
<thead>
<tr>
<th>Author</th>
<th>% Incontinence</th>
<th>% Post TURP</th>
<th>% No TURP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beyer et al. [268]</td>
<td>1</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Blasko et al. [269]</td>
<td>6</td>
<td>17</td>
<td>0</td>
</tr>
<tr>
<td>Stock et al. [270]</td>
<td>0</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Wallner et al. [271]</td>
<td>0</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Kaye et al. [272]</td>
<td>4</td>
<td>11</td>
<td>1</td>
</tr>
<tr>
<td>Blasko et al. [273]</td>
<td>13</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>Hu and Wallner [274]</td>
<td>6</td>
<td>70</td>
<td>-</td>
</tr>
<tr>
<td>Benoit et al. [275]</td>
<td>6.6</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Merrick et al. [276]</td>
<td>0</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Crook et al. [277]</td>
<td>5.6</td>
<td>13</td>
<td>-</td>
</tr>
<tr>
<td>Talcott et al. [278]</td>
<td>105</td>
<td>83</td>
<td>39</td>
</tr>
<tr>
<td>Bottomley et al. [279]</td>
<td>1.5</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

* Implant plus external beam radiation
coagulative necrosis of the tissue without damaging the structures intervening between the transrectal probe and the target tissue [296]. Recent reports of efficacy also include morbidity. In a systematic review involving 37 articles/abstracts Rebillard et al. [297] reported that stress incontinence occurs in 6-28%, urethra/bladder neck stenosis in 1-31%, and rectourethral fistula in 0-3% of treated patients. With improvements in techniques the risk of complications is decreasing [297].

4. INCONTINENCE AFTER NEOBLADDER CONSTRUCTION

The incidence of incontinence after neobladder construction following radical cystectomy for bladder cancer ranges from 85 to 100% during the day and 55 to 100% at night (Table 10 [298-310]). 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 [179] reported on 8 patients treated with the AUS for persistent sphincter weakness incontinence. Six of these underwent revisions, 3 for infection 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 [311] 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. The bone-anchored sling has been reported for one case [312]. Collagen has only been reported in women following neobladder construction [313].

In summary there are not enough data upon which to recommend definitive surgical therapy, although the artificial sphincter looks reasonable. (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 [314, 315] 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 [176] reported on 27 patients after urethral or bladder neck strictures. The revision rate was 41% and the continence rate was 85%. In a subsequent report from this centre on reoperations the patients with traumatic injuries were not discussed separately [316]. In Montague’s [178] 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 [179] reported on only one patient out of 81 with a traumatic urethral injury. This patient was dry and required no revisions. Venn

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Table 9. Lower urinary tract complications after cryosurgery for prostate cancer

<table>
<thead>
<tr>
<th>Author</th>
<th>N</th>
<th>% Incontinent</th>
<th>% Bladder outlet obstruction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shinohara et al. [282]</td>
<td>102</td>
<td>5</td>
<td>23</td>
</tr>
<tr>
<td>Bahn et al. [283]</td>
<td>210</td>
<td>3</td>
<td>9</td>
</tr>
<tr>
<td>Cox and Crawford [284]</td>
<td>63</td>
<td>27</td>
<td>29</td>
</tr>
<tr>
<td>Wieder et al. [285]</td>
<td>83</td>
<td>2.5</td>
<td>13</td>
</tr>
<tr>
<td>Cohen et al. [286]</td>
<td>239</td>
<td>4</td>
<td>2.2</td>
</tr>
<tr>
<td>Coogan and McKiel [287]</td>
<td>95</td>
<td>3.5</td>
<td>6</td>
</tr>
<tr>
<td>Sosa et al. [288]</td>
<td>1467</td>
<td>11</td>
<td>6.8</td>
</tr>
<tr>
<td>Long et al. [289]</td>
<td>145</td>
<td>83/2.0*</td>
<td>17.2</td>
</tr>
<tr>
<td>Pisters et al. [290]</td>
<td>150</td>
<td>60</td>
<td>43</td>
</tr>
<tr>
<td>Derakhshani et al. [291]</td>
<td>48</td>
<td>10.4</td>
<td>22.9</td>
</tr>
<tr>
<td>Long et al. [292]</td>
<td>975</td>
<td>7.5</td>
<td>13</td>
</tr>
<tr>
<td>De la Taille et al. [293]</td>
<td>43</td>
<td>9</td>
<td>4</td>
</tr>
<tr>
<td>Robinson et al. [294]</td>
<td>46</td>
<td>29 (urinary bother)</td>
<td>-</td>
</tr>
</tbody>
</table>

*Previously radiated/not previously radiated
at el. [263] reported on 2 with pelvic trauma out of a total of 70. (Level of evidence 3; Grade of recommendation C)

Bladder neck reconstruction by excising the scar and narrowing the calibre was reported by Iselin and Webster [317] 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 [318] (Level of evidence 3; Grade of recommendation C)

For patients with severe bladder neck strictures and incontinence after prostate surgery Meulen et al. [319] and the group from Baylor [187, 320] reported on the use of a Urolume stent with a bulbar artificial sphincter. Alternative management with perineal urethroplasty and subsequent artificial sphincter placement in 6 patients was reported by Simonato et al. [321] (Level of evidence 3; Grade of recommendation C)

Achieving continence and protecting the upper urinary tract are important goals of reconstruction in patients with exstrophy-epispadias complex. However, these tasks remain formidable challenge for pediatric urologists. Urinary incontinence [322, 323] and other voiding problems [324, 325] 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 7 years, the long-term follow-up data into adulthood are still lacking [322, 326], and there have been no significant changes in the management of urinary incontinence. Furthermore, the definition of continence differs between studies. Despite the devastating nature of this disease, there have been few studies addressing quality of life issue and psychological assessment in patients with exstrophy-epispadias complex. Lee et al. surveyed 208 patients of which only 24 were 18 years or older. They found that of those older than 20 years all women and but only 60% of males had close friendships [327].
Published materials consist mainly of retrospective reviews of experience at various centers. Even major institutions struggle to gather large series of patients. Thus, we are still left with mainly 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 end of this section.

I. 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 [323, 328-332] although the staged approach has undergone significant changes since first advocated by Jeffs et al [328]. Success rates for staged functional closure are high with continence rates reaching 75% to 90% [328-330]. However, these results were based on highly selected groups of patients and others failed to achieve such results. Continence rates of only 10% to 30% were reported with the staged approach [333, 334]. Complete primary repair described by Grady and Mitchell combined primary bladder closure with epispadias repair in one stage in neonates [335]. 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 because of breakthrough urinary tract infections. A recent report from another institution has also shown that complete repair of exstrophy is feasible in neonates and older children after failed initial closure, with acceptable morbidity [336]. 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 [336]. However, we will have to wait for long-term results from those 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 [337, 338]. 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 [337, 338]. Low pressure rectal reservoirs in children with bladder extrophy have also provided excellent long-term outcome in continence (100%) and preservation of the upper tract (97%) [339]. 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 [339]. 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 [339].

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 [328, 329]. The classic Young-Dees-Leadbetter technique has been modified in several ways [329, 332, 340]. 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 [325]. A report from the Johns Hopkins group [329] describes that 77% of patients are completely dry by day and by 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 preoperative bladder capacity of greater than 85 cc had a better outcome [329]. However, subjective success with continence and emptying does not necessarily correlate with objective findings [325]. 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 rates of less than 10 ml/sec in 70%, postvoid residual more than 33% of capacity in 50% and acute urinary retention in 17% [325]. 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 [341]. Similarly Burki et al. reported redo bladder neck reconstruction in 30 patients and all required intermittent catheterization [342]. 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 improvement 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 [341].

c) Urodynamic evaluation
There are several reports on urodynamic evaluation in patients who underwent bladder neck reconstruction [343-345]. The majority of closed exstrophy bladders have normal filling dynamics before bladder neck reconstruction [344]. However, bladder abnormalities are very common after bladder neck reconstruction, with about 50% incidence of poor compliance and detrusor overactivity [343-345]. 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 [323, 346, 347]. 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 [337-339, 341, 347-352]. 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 for the individualization of treatment to optimize the chance of a successful outcome [345]. Multiple available reconstructive options may be considered to optimize continence outcome [353].

a) Augmentation cystoplasty
The late 1980s and early 1990s witnessed the more liberal use of bladder augmentation coupled with the option of a catheterizable appendicovesicostomy (Mitrofanoff procedure). The overall rate of bladder augmentation in patients with exstrophy-epispadias complex has been 22% to 40% [323, 325]. Preservation of the native bladder template has been emphasized by the Johns Hopkins group and others [330, 354]. 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 structure for reimplantation than a subtaenial tunnel of the bowel [330].

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 [355], decreased linear growth [356], and hematuria-dysuria syndrome (in the case of stomach) [357]. 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 [358]. Gastrointestinal composite reservoirs, i.e. those made of a combination of stomach and other intestinal segments, may be considered to achieve electrolyte neutrality by contrasting electrolyte movements across the stomach and bowel [348].

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 [352]. 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 [359]. 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 [341]. However, the success of bladder neck closure is dependent in part upon patients' compliance with intermittent catheterization [352]. In addition, those who have undergone bladder neck closure are at an increased risk for bladder stones [352].

c) Urinary diversion
Regardless of the type of continent urinary diversion used, most series demonstrate excellent success rates around 95% [359]. 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 a catheterizable stoma [337, 338]. However, taking into account the long-term negative impact of a rectal reservoir on the metabolic milieu and bone density [339] and a high risk of neoplasia in those who have been exposed to the mixing of urine and faeces in a colorectal reservoir [360], 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 or an artificial urinary sphincter [352]. 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 [323]. A vascularized gracilis muscle sling, to wrap around the compromised bladder neck of incontinent patients has been reported as salvage surgery [350]. Limited success has been reported with the use of bulking agents 361, 362].

3. RECOMMENDATIONS

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

- 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 Terminology Report of the International Continence Society the overactive bladder (OAB) syndrome refers to the symptoms of urgency, with or without urge incontinence, usually with frequency and nocturia [363]. Detrusor overactivity (DO) was redefined to indicate the urodynamic observation characterized by involuntary detrusor contractions during the filling phase that may be spontaneous or provoked. Idiopathic Detrusor Overactivity (IDO) exists when there is no defined cause and replaces the term “detrusor instability”. Neurogenic Detrusor Overactivity (NDO) is seen when there is a relevant neurological condition and replaced the term “detrusor hyperreflexia”. The criterion for considering detrusor overactivity as idiopathic is questioned, as Ahlberg et al found that 82% of patients initially considered idiopathic on careful searching actually had pathology potentially leading to the problem [364].

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% [365]. In the asymptomatic elderly, detrusor overactivity once again becomes common, occurring in 50% of men over 70 [366]. In the symptomatic elderly, over 75 years old, it can reach 90% in men [367]. 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.

Magnetic stimulation may play a role in the non-invasive treatment of DO [368, 369]. Bradshaw et al. demonstrated an effect on cystometry of magnetic stimulation and found an improvement in urodynamic parameters but no consistent change in OAB symptoms [370]. Almeida et al. [371] in a prospective urodynamic controlled study of 91 women with UI, found an improvement on DO only in patients with initial bladder contractions <15 cm H2O. There are no other data available on the subject.

For symptoms that are refractory to conventional means, 4 interventional treatments have been reported: intravesical resiniferatoxin, botulinum-A toxin detrusor injections, neuromodulation, and bladder augmentation.
\textit{a) Resiniferatoxin}

The use of intravesical neuromodulatory drugs such as capsicain and resiniferatoxin was extended to DO of non-neurologic origin after the suggestion that its etiology involved the enhancement of the C-fiber mediated spinal micturition reflex [372] and emerged as a minimally invasive procedure: the results are shown in Table 11 [373-380]. In spite of promising results, it is still considered experimental and more clinical studies are necessary for it to be licensed [381].

The mechanism of action is still under study. The mean bladder perception threshold is increased only in patients with clinical improvement [382]. The complexity of the mechanism is demonstrated by the presence of vanilliod receptors not only on sensory fibers but also in bladder urothelium and smooth muscle cells [379] and by ineffectiveness in treating an overactive bladder from idiopathic causes or suprapontine lesions with no vanilliod-sensitive fiber-mediated reflex [383]. It has been suggested that over expression of transient receptor potential vanilliod subfamily 1 in the bladder predicts the response [384]. A well designed double-blind placebo-controlled study revealed no difference between placebo ethanol 10% saline solution and 50 nM resiniferatoxin, nevertheless both treatments showed improvement in symptoms of women with IDO [380]. Some placebo-controlled studies either did a quasi randomization [385] or did not explain how it was done [379]. Patients with increased bladder sensation without DO presented some improvement in symptoms in a small non placebo controlled series [386]. (levels of evidence 1 – 4; Grade of recommendation D, two level 1 studies have contradictory conclusions [379, 384]

\textit{b) Botulinum-A toxin injection in the bladder}

The minimal invasiveness of this method makes it very attractive but long term results in IDO are lacking (Table 12 [387-403]). The effects of its use are still not fully recognized [404], with possible systemic consequences [405-407], such as generalized muscle weakness in two patients treated for neurogenic bladder overactivity, and the development of resistance to the drug [408, 409]. The FDA made a public notification of adverse reactions linked to Botox use in February 2008, in approved and nonapproved usages. The agency is currently reviewing safety data from clinical studies to further communicate to the public its conclusions [410]. Most of the initial experience comes from its use in neurogenic bladders [411-414], with favorable results. Information about its use in children is scarce [415]. A randomized study comparing the results of botulinum-A toxin injections to intravesical resiniferatoxin in NDO showed superior clinical and urodynamic benefit with the use of botulinum-A toxin [414]. The need for reinjectons seems to be overcome by the significant improvement in quality of life of these patients [416], and is likely to be cost-effective [417]. The use of botulinum toxin B is less efficient, with a duration of action of about 10 weeks [418].

The optimal site of injections, including or not including the trigone, is still under debate [419]. Kuo in 2007[39] published a study comparing the injections into the detrusor, suburothelial area, and bladder base, with the last location improving urgency but not increasing capacity. Most studies on idiopathic overactive bladder have been done in women [393, 394]. Data are lacking on dose, concentration, site(s), numbers of injections and long-term efficacy and side effects. Attempts to determine whether poor responders could be predicted from preoperative urodynamic parameters showed only a very high maximal detrusor pressure over 110 cm H2O as an unfavorable predictor when using 200 units [401]. Studies in women suggest a longer duration of action than its mere motor-nerve blocking potency can explain [394]. Therefore, a dual mechanism of action has been proposed: in addition to binding to cholinergic terminals, it might also affect afferent nerve transmission, thereby decreasing urgency [420, 421].

There are two commonly marketed forms of botulinum toxin-A (Botox and Dysport) and they require different doses to achieve similar results, in a proportion around 1:3 [422]. The first report using Dysport in refractory IDO was only recently published with similar results to Botox [393]. In a study using type A neurotoxin, purified by a procedure using a lactose gel column, improvements were seen in 89% of patients treated for incontinence due to IDO and NDO [396].

Many studies with botulinum toxin detrusor injection use different outcome measures for results and are variable for the presence of residual urine and the need for intermittent catheterization, but 6-75% of cases may present high post void residual urine [394, 396, 398, 401]. Besides being an alternative for treatment of refractory DO, currently available data do not show superiority of any specific treatment plan, and therapy options should be tailored to the specific patient and physician preference [423]. Higher doses such as 200 units in IDO resulted in incomplete emptying, necessitating intermittent catheterization in 6 out of 16 patients (37.5%) in one study [401]. Sahai suggests a careful follow up of the patients after the injections, starting IC in symptomatic patients if postvoid residual urine is more than 100-150 ml [424].

Many reports do not separate genders and mix neurogenic and idiopathic etiologies. A large number of publications are reviews of the literature [425-435]. There is one randomized double blind placebo controlled trial showing favorable difference against saline injections for frequency and incontinence, but not for urgency [401]. (Most levels of evidence 3, with one level 2; Grade of recommendation C)
<table>
<thead>
<tr>
<th>Author</th>
<th>No.</th>
<th>Improvement</th>
<th>Duration of effect</th>
<th>Drug and dose</th>
<th>Side effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cruz et al. [373]</td>
<td>3</td>
<td>71% continence (overall total of 14) and 21% improvement</td>
<td>Up to 18 months</td>
<td>Capsaicin 125 ml of 30% alcohol in saline containing 1 mM Intense burning sensation</td>
<td></td>
</tr>
<tr>
<td>Kuo [374]</td>
<td>13</td>
<td>5 (38.5%)</td>
<td>2 to 9 months</td>
<td>RTX 10 ml of 100 nM RTX in 10% ethanol for 40 min</td>
<td></td>
</tr>
<tr>
<td>Kuo [378]</td>
<td>(23)</td>
<td>(11 of 19) (58%)</td>
<td>Average 5 months</td>
<td>10nM RTX weekly 3 to 4 times 4 withdrew due to side effects. Significant worsening of emptying</td>
<td></td>
</tr>
<tr>
<td>Kuo et al. [379]</td>
<td>17</td>
<td>Vehicle 2(9) 22% RTX 5 (8) 63%</td>
<td>6 months</td>
<td>Vehicle or 4 weekly 10 nM RTX</td>
<td></td>
</tr>
<tr>
<td>Liu and Kuo [384]</td>
<td>28</td>
<td>14 (50%)</td>
<td>10 nM RTX weakly 4 weeks</td>
<td>Transient receptor potential vanilloid subfamily 1 overexpressed in the responders</td>
<td></td>
</tr>
<tr>
<td>Palma et al. [375]</td>
<td>25 females with idiopathic urgency incontinence</td>
<td>10 (40%) disappearance of urgency incontinence</td>
<td>1 month evaluation only</td>
<td>50 nM RTX</td>
<td></td>
</tr>
<tr>
<td>Rios et al. [380]</td>
<td>58 females With IDO</td>
<td>43% RTX 35 % Placebo Vehicle Improvement - equal (p=0.439)</td>
<td>1 month first evaluation</td>
<td>50nM RTX or 10% ethanol saline solution Randomized double-blind placebo controlled</td>
<td></td>
</tr>
<tr>
<td>Silva et al. [377]</td>
<td>13 IDO (2 men 11 women) (12 incont.)</td>
<td>11 improved (91%) in incontinence 3 (25%) dry</td>
<td>3 months follow-up</td>
<td>100 ml 50nM RTX solution 10% ethanol in saline for 30 min No retention or other problems</td>
<td></td>
</tr>
<tr>
<td>Silva et al.[385]</td>
<td>17 IDO (out of 23)</td>
<td>Vehicle 9 (39%) RTX 14 (60%)</td>
<td>Pre-test with vehicle only followed by RTX Vehicle followed by 100 ml 50nM RTX (patients enrolled in 2005)</td>
<td>No separation of NDO and IDO No RETENTION OR OTHER PROBLEMS</td>
<td></td>
</tr>
<tr>
<td>Yokoyama et al. [382]</td>
<td>10 (4 men)</td>
<td>5 (2 dry) 50%</td>
<td>3 months follow-up</td>
<td>100 ml 50nM RTX for 30 min Neurometer before and at 30 days</td>
<td></td>
</tr>
<tr>
<td>Author</td>
<td>No.</td>
<td>Type of patients</td>
<td>Dose</td>
<td>No. punctures</td>
<td>Results</td>
</tr>
<tr>
<td>-------------------------</td>
<td>-----</td>
<td>------------------</td>
<td>------------</td>
<td>---------------</td>
<td>----------------------------------------------</td>
</tr>
<tr>
<td>Harper et al. 2003 [387]</td>
<td>39</td>
<td>(13 men and 26 women)</td>
<td>200 idiopath</td>
<td>20 to 30 sparing the trigone</td>
<td>Increase max bladder volume 174 to 588 ml</td>
</tr>
<tr>
<td>Loch et al. 2003 [388]</td>
<td>30</td>
<td>Neurogenic and idiopathic</td>
<td>200 U</td>
<td>20 injections sparing the trigone</td>
<td>Significant improvement in 67% of the patients &gt; residual urge</td>
</tr>
<tr>
<td>Radziszewski et al. 2002 [389]</td>
<td>12 (6 female and 6 male)</td>
<td>Only idiopathic</td>
<td>Up to 300 U</td>
<td>10-15 injections sparing the trigone</td>
<td>1 months follow-up 100% success no residual</td>
</tr>
<tr>
<td>Rackley et al. 2004 [402]</td>
<td>18 women</td>
<td>IDO</td>
<td>200-300 U (Botox)</td>
<td>Each 100 U in 1 cc saline, 0.1 cc injections</td>
<td>Improvement 40% frequency 30% urgency</td>
</tr>
<tr>
<td>Rapp et al. 2004 [390]</td>
<td>35</td>
<td>(29 females and 6 males)</td>
<td>300 U</td>
<td>30 injections including trigone</td>
<td>34% resolution 26% improvement</td>
</tr>
<tr>
<td>Kuo, 2004 [391]</td>
<td>30</td>
<td>(12 females and 18 males)</td>
<td>200 U</td>
<td>40 injections sparing the trigone</td>
<td>26% resolution 46% improvement</td>
</tr>
<tr>
<td>Chancellor et al. 2003 [392]</td>
<td>10 (2 males and 8 females)</td>
<td>Only idiopathic</td>
<td>100-300 U</td>
<td>20-30 injections only in bladder base and trigone</td>
<td>80% improvement</td>
</tr>
<tr>
<td>Rajkumar et al. 2005 [396]</td>
<td>15 women</td>
<td>IDO</td>
<td>300 U (Botox)</td>
<td>30 ml – 30 injections</td>
<td>93% improvement</td>
</tr>
<tr>
<td>Popat et al. 2005 [397]</td>
<td>31 (18 women and 13 men)</td>
<td>IDO</td>
<td>200 U (Botox)</td>
<td>20 ml – 20 injections</td>
<td>57 % dry at 4 months</td>
</tr>
<tr>
<td>Kessler et al. 2005 [403]</td>
<td>11 patients (no gender information – 8 men in total of 22 patients)</td>
<td>IDO</td>
<td>300 U (Botox)</td>
<td>30 ml – 30 injections sparing the trigone</td>
<td>91% dry 5 months duration</td>
</tr>
<tr>
<td>Werner et al. 2005 [649]</td>
<td>26 women</td>
<td>Only IDO</td>
<td>100 U (Botox)</td>
<td>30 ml-30 injections</td>
<td>65 % dry at 12 weeks 60% dry at 36</td>
</tr>
</tbody>
</table>
c) Electrical stimulation and neuromodulation

Electrical stimulation of the genital area was first used to control incontinence due to DO on an empirical basis for different etiologies [436]. Later, it was suggested that reflex sphincteric contraction induced by electrical stimulation can promote an inhibitory effect on detrusor activity, thus suppressing detrusor overactivity [437]. Many studies of external electrical stimulation for bladder inhibition of idiopathic urgency incontinence have been published, mainly in female patients [438-445]. The results vary from 45% to 85% success, with a mean of 38%, and 26% improved. Electrodes implanted in the pelvic floor, have not yielded good results [443].

Neuromodulation of sacral nerves has been reported as alternative therapy for urgency incontinence, urinary retention, and chronic pelvic pain. Good results have been published in treating neurogenic bladder dysfunction [446, 447]. The working mechanism of neuromodulation in the treatment of lower tract dysfunction is still unknown [448, 449]. A suggested mechanism is somatic afferent inhibition of sensory processing in the spinal cord [450, 451], therefore it may be a centrally acting treatment modality different from botulinum toxin, which is an end-organ therapy that specifically targets the bladder [452].

Long-term results suggest a sustained effect on restoring voiding in appropriately selected cases, but a revision rate of 42% at 5-year follow up remains a problem [453]. Its use in refractory idiopathic urgency incontinence has been limited to few patients, mostly women. Bosch and Groen [454] 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 [455]. Shaker and Hassouna [456] implanted 18 patients with refractory urinary urgency incontinence, but only 2 were in men. Groen, Bosch and van Mastrigt reviewed 33 implanted women and found no effect on urethral resistance and bladder contraction strength as consequence of the depressant effect of sacral (S3) nerve neuromodulation on detrusor overactivity [457]. Groenendijk et al. in a retrospective study for the Sacral Nerve Stimulation Study Group, reported urodynamic aspects of 111 patients implanted, but only 8 men were included [458]. They found a better result on urgency incontinence in patients without DO. The difference was not significant. This tendency was also found by South et al. in 67 women implanted [459]. Clinical or urodynamic values to predict the outcome of sacral nerve stimulation has been difficult to define. Evaluation of 19 women suggested that urethral instability seemed to be a good parameter to predict a favourable outcome [460].

Some studies do not specify the etiology of the DO and neurogenic and non-neurogenic causes are grouped together [456]. Some reports focus on technical or specific aspects of the procedure and the same patients may be included in different publications [458, 461, 462]. Implantation in children may be feasible in selected cases [463, 464] and poorer results are expected in older women [102]. The outcome in older men is unknown since there are no reports.

Table 13 [403, 453, 465-472] shows some recent studies.

Some reports are literature reviews [449, 473-475] or detail technical modifications [476, 477]. There is one systematic review on efficacy and safety of sacral nerve stimulation for urgency incontinence, but 13 of the articles analyzed are abstracts and it is also difficult to ascertain whether the same patients are included in different publications [478].

There are some publications with level 1[465, 466] or 2 [455, 468, 469] evidence and with a grade of recommendation B. However, due to relatively few men in the clinical trials, and poor results in one of the prospective trials, its general applicability to men with urgency incontinence may be limited. Level of evidence 3. Grade of recommendation D (due to lack of evidence)

d) Surgical treatment by detrusor 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 detrusor myectomy has been reported as an alternative to augmentation in neurogenic and non-neurogenic dysfunction. Table 14 [479-481] shows results of this treatment in patients with non-neurogenic detrusor overactivity. There are few long term results available [481]. Additional and longer term experience is still required to properly assess this procedure. (Level of evidence 3; grade of recommendation C-D)

Enterocystoplasty results are detailed in Table 15 [480, 482-488], which includes both male and female patients. Some publications are not clear about the type of surgery specifically done in IDO and about the gender [488]. Good results vary from 58% to 88%, with an average of 77%. Approximately 10 to 75% 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 the 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. (Level of evidence 3; grade of recommendation C)
### Table 13. Neuromodulation for treatment of refractory urgency incontinence due to detrusor overactivity (males and females)

<table>
<thead>
<tr>
<th>Authors</th>
<th>N</th>
<th>Success (dry)</th>
<th>Improved</th>
<th>Control group</th>
<th>Study and comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schmidt et al. [465]</td>
<td>34</td>
<td>47%</td>
<td>29%</td>
<td>42</td>
<td>prospective randomized</td>
</tr>
<tr>
<td>Weil et al. [466]</td>
<td>21</td>
<td>56%</td>
<td>19%</td>
<td>23</td>
<td>prospective randomized</td>
</tr>
<tr>
<td>Bosch et al. [467]</td>
<td>34</td>
<td>38%</td>
<td>21%</td>
<td>38 (77.6%)</td>
<td>prospective longitudinal</td>
</tr>
<tr>
<td></td>
<td>(females) 6 (males)</td>
<td>16%</td>
<td>16%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Siegel et al. [468]</td>
<td>41</td>
<td>46%</td>
<td>19%</td>
<td></td>
<td>prospective cohort</td>
</tr>
<tr>
<td>van Kerrebroeck et al. [453]</td>
<td>105</td>
<td>58% for UI</td>
<td>40% for Frequency</td>
<td>5-year follow up (non randomized)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(do not discriminate gender)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grunewald et al. [469]</td>
<td>18</td>
<td>39%</td>
<td>33%</td>
<td></td>
<td>prospective</td>
</tr>
<tr>
<td>Aboseif et al. [470]</td>
<td>43</td>
<td>77%</td>
<td></td>
<td></td>
<td>not clear about etiology</td>
</tr>
<tr>
<td></td>
<td>(5 males)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hedlund et al. [471]</td>
<td>13</td>
<td>61.5%</td>
<td></td>
<td></td>
<td>2 men included, both dry</td>
</tr>
<tr>
<td>Roupret et al. [472]</td>
<td>6</td>
<td>17%</td>
<td>67%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(all female)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kessler et al. [403]</td>
<td>71</td>
<td>70%</td>
<td></td>
<td></td>
<td>average follow up 2 years Gender not specifically discriminated (about 13% of all are males)</td>
</tr>
<tr>
<td></td>
<td>with urgency incontinence (in total of 91)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Author</th>
<th>Idiopathic detrusor overactivity</th>
<th>Good results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Swami et al. [479] *</td>
<td>17</td>
<td>12</td>
</tr>
<tr>
<td>Kumar et al [481] **</td>
<td>24</td>
<td>19</td>
</tr>
<tr>
<td>Leng et al. [480]</td>
<td>8</td>
<td>7</td>
</tr>
<tr>
<td>TOTAL</td>
<td>49</td>
<td>38 (77.6%)</td>
</tr>
</tbody>
</table>

*short term followup

**longer term follow-up of the same series, 45% required IC
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 as a result of progressive decrease in bladder 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 urodynamics. The causes can be congenital or acquired. Acquired causes include multiple surgeries, inflammatory processes (chronic cystitis, interstitial cystitis, tuberculosis, schistosomiasis, and chemical cystitis) or following 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 [489]. Bladder augmentation seems to offer reasonable results in these cases.

Similarly, small fibrotic bladders due to other etiologies can be treated successfully with enterocystoplasty. The results of this surgery are presented in Table 16 [488, 490-516]. The results are similar in all etiologies except for radiation. The poorer results after radiation may be 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 cystoplasty 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 patients who have undergone 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 except one are retrospective case series. The report by Shakespeare et al. [517] is from a prospectively collected data base of patients treated with radiotherapy for prostate cancer. (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 [518] 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.

---

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

<table>
<thead>
<tr>
<th>Authors</th>
<th>Detrusor overactivity</th>
<th>Good or moderate result</th>
<th>Bowel segment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hasan et al. [482]</td>
<td>35</td>
<td>19</td>
<td>46 ileum 2 colon</td>
</tr>
<tr>
<td>McInerney et al. [483]</td>
<td>50</td>
<td>44</td>
<td>13 colon</td>
</tr>
<tr>
<td>Bramble [484]</td>
<td>15</td>
<td>13</td>
<td>2 ileum</td>
</tr>
<tr>
<td>Sethia et al. [485]</td>
<td>11</td>
<td>9</td>
<td>ileum</td>
</tr>
<tr>
<td>Mundy and Stephenson [486]</td>
<td>40</td>
<td>30</td>
<td>ileum</td>
</tr>
<tr>
<td>Leng et al. [480]</td>
<td>2</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Edlund et al. [487]</td>
<td>25</td>
<td>19</td>
<td></td>
</tr>
<tr>
<td>Blaivas et al. [488]</td>
<td>9</td>
<td>9</td>
<td>Ileocaecal segment and ileum</td>
</tr>
<tr>
<td>Total</td>
<td>187</td>
<td>145 (78%)</td>
<td></td>
</tr>
</tbody>
</table>
### Table 16. Enterocystoplasty results for reduced bladder capacity

<table>
<thead>
<tr>
<th>Authors</th>
<th>Bilharziasis cystitis</th>
<th>Tuberculous cystitis</th>
<th>Radiation cystitis</th>
<th>Unknown cause</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total</td>
<td>Success</td>
<td>Total</td>
<td>Success</td>
</tr>
<tr>
<td>Smith et al.[490]</td>
<td>-</td>
<td>-</td>
<td>7</td>
<td>4</td>
</tr>
<tr>
<td>Kerr et al. [491]</td>
<td>-</td>
<td>-</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>Zimmn and Libertino [492]</td>
<td>-</td>
<td>-</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Dounis et al. [493]</td>
<td>-</td>
<td>-</td>
<td>31</td>
<td>27</td>
</tr>
<tr>
<td>Lunghi et al. [494]</td>
<td>-</td>
<td>-</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>Shawkhet and Muhsean [495]</td>
<td>8</td>
<td>8</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Whitmore and Gittes [496]</td>
<td>-</td>
<td>-</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>Chan et al. [497]</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Shirley et al. [498]</td>
<td>-</td>
<td>-</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Goodwin et al. [499]</td>
<td>-</td>
<td>-</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Winter and Goodwin [500]</td>
<td>-</td>
<td>-</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Fall and Nilsson [501]</td>
<td>-</td>
<td>-</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Goldwasser and Webster [502]</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Weinberg et al. [503]</td>
<td>-</td>
<td>-</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Novak [504]</td>
<td>-</td>
<td>-</td>
<td>11</td>
<td>11</td>
</tr>
<tr>
<td>Sayegh and Dimmette [505]</td>
<td>2</td>
<td>0</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Beduk et al. [506]</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Kuo [507]</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Kawamura et al. [508]</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Hradec [509]</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>El Otmany et al. [511]</td>
<td>-</td>
<td>-</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Yamada et al. [512]</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>Miyano et al. [513]</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Blaivas et al. [488]</td>
<td>-</td>
<td>-</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>de Figueiredo et al. [514]</td>
<td>-</td>
<td>-</td>
<td>25</td>
<td>20</td>
</tr>
<tr>
<td>Yashi et al. [515]</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Lima et al. [516]</td>
<td>-</td>
<td>-</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>10</td>
<td>8 (80%)</td>
<td>136</td>
<td>123 (90%)</td>
</tr>
</tbody>
</table>
Urethroperineal fistula, as a complication of open perineal prostate cryosurgery, occurs as an immediate perioperative complication in 10.7% [519]. Thomas et al. [520] retrospectively evaluated 250 patients after radical perineal prostatectomy and revealed only 1 (0.4%) urethroperineal fistula. Fahal et al. [521] published an unusual complication of mycetoma. The patient had an infection with Actinomadura madurae that involved abdominal wall, perineum and urethra. This resulted in urinary extravasation with a urethrocutaneous fistula.

c) Management of UCF

The diagnosis of UCF is made by physical examination, retrograde urethrography (Figure 3), urethroscopy, fistulography, urethral ultrasound or color Doppler imaging. Urethral sonography provides additional information about any involvement of the surrounding tissue, location of vessels and associated abnormalities such as a periurethral abscess [522].

Treatment of UCF usually requires urethroplasty techniques with modifications involving fistula excision and multiple layer closure [523]. (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 [524]: congenital, iatrogenic, traumatic, neoplastic, and inflammatory.

a) Congenital RUF

Endo et al. [525] 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 the 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 analyzed 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 [526].

b) Acquired RUF

Acquired RUF may occur after pelvic trauma, surgery of the prostate or rectum, pelvic cancer, radiation (either external beam or brachytherapy), cryosurgery, prostatic hyperthermia, prostatic high intensity focussed ultrasound (HIFU), inflammatory bowel disease affecting rectum, or rarely prostatic inflammation.

Benchekroun and co-workers [527] report a series of 11 RUF observed over a 25-year period. The etiologies 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: abdominoperineal (3 cases), perineal (2 cases), transperitoneal (1 case) or by transanosphincteric incision (1 case).

In 1972 Smith and Veenema [528] reported their 20-year experience with 160 patients undergoing radical retropubic prostatectomy (RRP) with an 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. [529] 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. [530] reported 23 (3.9%) rectal injuries during 589 RRP and cystoprostatectomy procedures. Eastham and Scardino [531] 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%.

Figure 3 : Urethrocutaneous fistula (Black Arrow) is demonstrated during voiding cystourethrogram after incision of paraurethral collection.
Nyam et al. [532] reviewed records of all patients who were diagnosed with RUF 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. Adenocarcinoma 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 fistulas 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 heterogenous 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.

Badalament et al. [533] managed one patient (0.4%) with a urethrorectal fistula after cryoablation therapy for prostate cancer. Zippe [534] reviewed preliminary results of prostate cryosurgery and reported a 2 to 5% incidence of RUF. Porter [519] found a 2.5% rate of RUF in 210 patients after TRUS-guided prostate cryosurgery and no urethroperineal fistulae. Ismail et al. [535] reported the experience of using salvage targeted cryoablation of the prostate (TCAP) in 100 patients for the recurrence after radiotherapy. The mean follow-up was 33.5 months and RUF occurred in 1%.

Montorsi et al. [536] reported a RUF 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. [537] summarized results of 31 patients with stage T1 or T2 prostatic carcinoma following CT guided transperineal I125 implants and reported that only one patient developed a prostatorectal fistula that was managed with an ileal conduit.

Fengler and Abcarian [538] published their experience of eight patients with RUF 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). Larson et al. [539] evaluated 5719 patients after radiation for prostate cancer. Ten had documented RUF. Lane et al. [540] treated 21 men with RUF following primary external beam radiotherapy and one after adjuvant external beam radiation therapy for prostate cancer. Time from the last radiation treatment to fistula presentation was 6 months to 20 years. Four patients underwent proctectomy with permanent fecal and urinary diversion. Successful fistula closure was achieved in the 9 patients who underwent urethral reconstruction. Chrouser et al. [541] identified a total of 51 patients with a history of external beam radiation for prostate cancer that subsequently had a urinary fistula. Of 20 patients meeting inclusion criteria, 30% received external beam RT alone, 30% received brachytherapy and 40% had received combined external beam RT/brachytherapy. Most fistulas (80%) were from the rectum to the urinary tract with an average diameter of 3.2 cm. Of patients with rectal fistulas 81% had a history of rectal stricture, urethral stricture, rectal biopsy, rectal argon beam therapy or transurethral prostate resection after radiation. All patients with rectourethral fistulas who achieved symptomatic resolution required urinary and fecal diversion.

Shakespeare et al. [517] reviewed the potential factors in fistula development and identified three cases (0.2%) of RUF among 1455 patients treated with prostate brachytherapy (BT), occurring at 19-27 months following BT. All these patients had BT monotherapy and had been investigated with endoscopy and low rectal biopsy. They concluded that gastrointestinal specialists should not perform biopsy of the anterior rectum in patients who have had BT unless there is a very high clinical suspicion of malignancy. Marguet et al. [542] described 6 cases of RUF in patients treated with brachytherapy plus external beam radiotherapy for localized prostate cancer and subsequent rectal biopsies or rectal surgery. Four patients underwent hyperbaric oxygen therapy, which failed. Three patients underwent fecal diversion with gracilis interposition flaps, and two underwent pelvic exenteration. They also concluded that biopsy of rectal ulcers in the clinical setting of combined radiotherapy should not be performed.

<table>
<thead>
<tr>
<th>Table 17. Causes of Rectourethral fistulae in 23 patients (Tiptaft [529])</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fractured pelvis with ruptured urethra</strong></td>
</tr>
<tr>
<td><strong>Direct trauma</strong></td>
</tr>
<tr>
<td><strong>Secondary to urethral stricture and sepsis</strong></td>
</tr>
<tr>
<td><strong>Tuberculosis</strong></td>
</tr>
<tr>
<td><strong>Iatrogenic</strong></td>
</tr>
<tr>
<td><strong>Iatrogenic causes</strong></td>
</tr>
<tr>
<td><strong>Urethral instrumentation</strong></td>
</tr>
<tr>
<td><strong>Transurethral prostatic surgery</strong></td>
</tr>
<tr>
<td><strong>Open prostatectomy</strong></td>
</tr>
<tr>
<td><strong>Flap urethroplasty</strong></td>
</tr>
<tr>
<td><strong>Colo-anal anastomosis</strong></td>
</tr>
<tr>
<td><strong>Abdominoperineal resection of rectum</strong></td>
</tr>
<tr>
<td><strong>Radiation therapy</strong></td>
</tr>
</tbody>
</table>
Badalament et al. [533] managed one patient (0.4%) with a urethrorectal fistula after cryoablation therapy for prostate cancer. Zippe [534] reviewed preliminary results of prostate cryosurgery and reported a 2 to 5% incidence of RUF. Porter [519] found a 2.5% rate of RUF in 210 patients after TRUS-guided prostate cryosurgery and no urethroperineal fistulae. Ismail et al. [535] reported the experience of using saline targeted cryoablation of the prostate (TCAP) in 100 patients for the recurrence after radiotherapy. The mean follow-up was 33.5 months and RUF occurred in 1%.

Montorsi et al. [536] reported a RUF 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.

Chang et al. [543] 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. [544] reported a very uncommon type of fistula between the large bowel and the prostatic urethra due to Crohn’s disease. Felipetto et al. [545] described a prostatocutaneous fistula as a complication of pseudomonas prostatitis.

Transrectal high-intensity focused ultrasound (HIFU) destroys prostate cells by coagulative necrosis of the tissue. Recent reports of efficacy also include morbidity. Rebillard et al. [297] reported RUF in 0-3% in a review involving 37 articles/abstracts.

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 placed into the bladder and then voided usually appears in the rectum on X-ray, are the most important diagnostic steps [522, 546] (Figure 4).

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 [547] 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, and 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.

e) Surgical Approaches

Surgical management for rectourinary fistulas remains a reconstructive challenge. Two-layer closure of the urethra and rectum with suture lines at right angles and with interposition of soft tissue (eg. omentum [548], gracilis muscle [549], or scrotal flap [550]) has been described. Surgical approaches include transabdominal, transvesical, or direct exposure of the RUF.

There are only a few guidelines to direct the surgeon to the most successful and least morbid technique. Rivera et al. [551] staged RUF as stage I—low (less than 4 cm from anal verge and nonirradiated), stage II—high (more than 4 cm from anal verge and nonirradiated), stage III—small (less than 2 cm irradiated fistula), stage IV—large (more than 2 cm irradiated fistula) and stage V—large (ischial decubitus fistula). Diverting colostomy was performed for stages
III to V 6 weeks before definitive therapy. Some of the patients in addition to the RUF will also have urethral strictures that have to managed. Reconstruction of both aspects to restore functional anatomy is possible with complex reconstructions [552].

The surgical approaches including the numbers of reported patients are listed in Table 18 [524, 527-530, 538, 546, 550, 553-569].

1. PERINEAL APPROACH

In 1926, Young [553] 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 [554], described suturing the levator muscle fibers together in the anterior midline when possible.

Goodwin et al. [555] 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. Singh et al. [570] described the management of a delayed post-traumatic RUF repaired via transperineal access without rectal or sphincteric transgression. An example of a preoperative and postoperative urethrogram is in Figure 5. Pratap et al. [571] described a simultaneous perineal and abdominal approach in a series of 8 patients with traumatic perineal injuries who had both complex urethral disruptions and RUF.

2. POSTERIOR SAGITTAL APPROACH

Kraske in 1885 [572] 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 coccyxctomy. 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 [558] 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.

3. POSTERIOR (PARASACROCOCCYGEAL) TRANSSHINTICER APPROACH

In 1969 Kilpatrick and Mason [560] 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 parasacrococcygeal (transsphincteric) incision especially to fistulae in the mid to lower rectum [538]. 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 the prostatic urethra. The undermining of rectal wall allows sufficient mobilization. After closure of the prostatic urethra it is recommended that the full-thickness rectal wall flaps are close in a “vest over pants” technique (Figure 6). It is important to make sure that the suture lines do not overlie each other. The procedure is completed by suture of the rectal wall and approximation of the sphincter muscles (Figure 7). Fengler and Abcarian [538] reported healing of RUF in all of 8 patients with the York-Mason approach. Bukowski et al. [562] managed 7 acquired recurrent RUF (3 after prostatectomy, 3 after trauma and 1 after perineal abscess) using York-Mason technique and a similar experience was described by Fournier et al. [551] in the management of a case of the urethro-prostato-rectal fistula after a gunshot wound.

Stephens and Middleton [559] 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 back to well vascularized tissue, and access to several vascularized flaps for interposition between the repaired urinary and gastrointestinal tracts.

Culkin [565] reported preliminary experience with the transsphincteric, transanal surgical approach to correct acquired urethrococcygeal 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 urethrococcygeal fistula to surgery was 4 weeks to 4 years. Five men underwent excision and closure of a urethrococcygeal 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.

Dal Moro et al. [573] reviewed a 15-year experience using the York-Mason posterior sagittal transrectal approach to iatrogenic RUF in 7 patients. In one patient with Crohn’s disease the fistula recurred 11 years after the first surgery. The colostomy remained in place only in one patient with Crohn’s disease and in another with ulcerative rectocolitis.
<table>
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<tr>
<th>Approach</th>
<th>Author, Year</th>
<th>No. Pts</th>
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<tr>
<td>PERINEAL</td>
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<td></td>
<td>Young, 1926 553</td>
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<td></td>
<td>Lewis, 1947 554</td>
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<td></td>
<td>Goodwin, 1958 555</td>
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<td></td>
<td>Culp and Calhoon, 1964 524</td>
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<td></td>
<td>Smith and Veenema, 1972 528</td>
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<tr>
<td></td>
<td>Youssef, 1999 556 (perineal dartos flap)</td>
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<td>Benchekroun, 1999 527</td>
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<td>Ng, 2004 557 (buccal graft)</td>
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<td>POSTERIOR - SAGITTAL</td>
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<td>POSTERIOR – TRANSSPHINCTERIC</td>
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<td>Kilpatrick and Mason, 1969 560</td>
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<td></td>
<td>Culp, 1964 524</td>
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<td>Fengler, 1997 538</td>
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<td>Fournier, 1996 561</td>
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<td></td>
<td>Bukowski, 1995 562</td>
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<td>TRANSANAL</td>
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<td></td>
<td>Parks and Motson, 1983 564</td>
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<td>Tiptaft, 1983 529</td>
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<td>Noldus, 1997 530</td>
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<td>Culkin, 2003 565</td>
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<td>COMBINED (posterior transssphincteric anterior rectal wall advancement)</td>
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<td>ANTERIOR TRANSANORECTAL</td>
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<td>Zinman, 2003 567</td>
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<td>ENDOSCOPIC</td>
<td>Wilbert, 1996 568</td>
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<td>Bardari, 2001569</td>
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Figure 5: A. Cystogram demonstrates RUF caused by a TURP. Negative shadow from Foley catheter is seen in the bladder. B. Retrograde urethrogram after transperineal closure of RUF.
Erickson et al. [574] reported a novel surgical technique used to repair a rectourethral fistula associated with two short-segment urethral strictures located in the anterior and posterior segments of the urethra in a patient with prior unsuccessful repairs. The anterior urethral stricture was reconstructed with a ventral onlay of buccal mucosa in the exaggerated lithotomy position. In a modified prone position, the rectourethral fistula was repaired using the transrectal transsphincteric (York-Mason) technique and the posterior urethral stricture with a radial forearm fasciocutaneous free flap which was anastomosed to the inferior gluteal artery and vein. The coexistence of a rectourethral fistula and distal urethral stricture requires simultaneous repair, because the urethral pressure from the distal obstruction may compromise fistula closure.

4. TRANSANAL APPROACH

Parks and Motson [564] 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 8 [575] and 9). 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. [529] 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. [530] reported 23 patients (3.9%) with rectal injury during 589 RP and cystoprostatectomies. 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. [546] 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 anoanal canals were normal.

5. ANTERIOR TRANSPHINCTERIC, TRANSANAL SURGICAL APPROACH (ASTRA)

In 1973 Gecelter [566] 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. Castillo et al. [576] reviewed their first 110 consecutive laparoscopic extraperitoneal radical prostatectomies and reported 3 RUF. Only one was cured with conservative management. The other 2 patients were repaired by anterior transsphincteric, transanal surgical approach (ASTRA).

6. ENDOSCOPIC APPROACH

Wilbert et al. [568] reported two patients with RUF who were repaired endoscopically transanally. The
Figure 8: Transanal repair of rectourethral fistula [575]. 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 9. 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 (Black arrow). B. Intraoperative photograph of transanal rectourethral fistula repair. The anus is held open by the ring retractor to permit direct access to the fistula. C. Intraoperative view of the rectal mucosal sutures in the rectourethral fistula repair. 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.
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.

Bardari et al. [569] used cyanoacrilic biological glue to close one prostatic-perineal fistula complicating an abdominoperineal resection of rectum and one persistent neobladder-ileal fistula. The biologic sealant was administrated endoscopically through an open-end 6F ureteral catheter. Quinlan et al. [577] presented the case of an iatrogenic fistula in a 71-year-old man treated by a transanal endoscopic microsurgical (TEM) approach, without recourse to a stoma. Bochove-Overgaauw et al. [578] reported successful repair of 1 of 2 RUF with transanal endoscopic microsurgery (TEM). The RUF occurred after laparoscopic radical prostatectomy.

7. OTHER MODIFICATIONS

Youssef et al. [556] 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 in 4. The fistula was associated with a urethral stricture in 4 cases. A perineal approach was used and combined with a transsymphysal 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. Varma et al. [579] also concluded that dartos muscle interposition is a straightforward technique that can result in successful fistula repair, but should not be used in immunocompromised patients or after radiation therapy.

Felipetto et al. [545] used human fibrin sealant (Tissucol) to close a prostatic-cutaneous fistula (as a complication of pseudomonas prostatitis). Venkatesh and Ramanujam [580] prospectively studied the efficacy of autologous fibrin glue for closure of recurrent anorectal fistulas. Overall success rate was 60% however patients with acquired immunodeficiency syndrome who had fistulas associated with the urinary tract failed to respond.

Finally Chirica et al. [581] reported their experience with coloanal sleeve anastomosis (Soave procedure) as a salvage procedure for complex rectourinary fistulas after radical prostatectomy or followed anterior resection for rectal cancer after radiochemotherapy. All eight patients had a temporary ileostomy, which was successfully reversed in 7.

f) Summary

A review of recent literature shows an increasing number of papers describing treatment. All available studies are retrospective cases and case series (level 3 evidence). 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. Conservative treatment is generally ineffective in the management of large RUF. Surgical intervention offers symptomatic relief and improved quality of life in most patients. All reports are still only retrospective case series (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 [582]. 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. Bradley, and G.W. Timm in 1973 [583]. 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

The results of an e-mail survey among urologists and gynecologists were previously published in the 3rd ICI, whereby 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. The price varied from $4000 to $10,000 USD. The high price in some countries at the time (Georgia, Hong-Kong, Romania and Saudi Arabia) precluded its use. Very few gynecologists implant the sphincter, probably since the majority of patients receiving the device are male.
2. INDICATIONS

The indication for AUS placement is for the treatment of SUI due to ISD that is persistently bothersome despite 6-12 months of active conservative management. As the most common cause of SUI in men is iatrogenic injury during prostate cancer surgery, it follows that the most common indication for AUS is post-prostatectomy incontinence (PPI). The use of the AUS for the treatment of PPI varies regionally. For example, within the United States, state-by-state use of the AUS ranges from 1% to 10% of all RRP patients, with an average of 6% of RRP patients ultimately undergoing AUS implantation. In 2005, 4,426 AUS units were sold in the United States, which represents approximately 1 unit per every 3 U.S. urologists [584]. Nearly half of all AUS implantations in the U.S. were indicated for SUI following prostate cancer surgery [184, 193, 263, 585, 586]. The remaining 50% of units are used for patients with neurogenic disorders (such as spina bifida or neurogenic ISD), for those with incontinence after transurethral resection of the prostate, and for females with ISD following failed sling surgery.

Previous radiotherapy to the pelvis is not a contraindication for AUS placement in males, [587] as the ultimate outcome seems to be similar in men whether or not they have received radiation therapy [236], 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 male patient [236]. Unlike in men, previous external beam radiation is a relative contra-indication for implantation in females due to a considerably higher erosion rate [263].

The compressive effect of the AUS is temporarily relieved when the patient squeezes the scrotal/labial pump, transferring fluid from the urethral cuff to the pressure-regulating balloon. Subsequently, the bladder can then empty either by bladder contraction and/or by abdominal straining. Accordingly, patients voiding with the Valsalva manoeuvre because of an underactive or neurologically acontractile bladder, do not seem to be at an increased risk of complications [588]. It should also be noted that patients with previous anti-incontinence procedures show a significantly higher explantation rate [589].

Clinical experience suggests that enterocystoplasty or gastrocystoplasty can be done simultaneously with the implantation of the AUS [590, 591]. However, AUS placement at the time of cystoplasty is associated with earlier infections, especially during the first 3 years post-operatively [592]. In the long-term (> 3 years) the infection rate is the same whether the AUS is implanted first or after the time of cystoplasty, AUS can also be successfully implanted in patients after bladder substitution [311], and in those with locally recurrent prostate cancer with a relatively good prognosis [593], or those with severe post-radical prostatectomy anastomotic stricture in whom a stent has been placed previously [320].

Finally, advanced age is not a contra-indication to AUS placement. A retrospective analysis by O’Connor and colleagues of a cohort of men over age 75, revealed excellent success rates, with 21 of 29 men (72%) achieving successful continence. Revision rate was 14% at an average of 5 years follow-up, with 14% requiring explantation, and 21% requiring device deactivation due to deterioration in overall health preventing proper use of the AUS at an average of 47 months after placement [235].

3. SURGICAL TECHNIQUES

The original technique of implantation is illustrated in Figure 10. 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. A relatively 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 [223]. Alternatively, the pressure-regulating balloon may be placed through a separate inguinal incision, with the cuff and control pump placed via a single trans-scrotal incision, with the connections among scrotal pump, balloon reservoir, and urethral cuff tubing made in the usual inguinal incision. While the trans-scrotal approach potentially minimizes the invasiveness of the AUS surgery, by limiting the surgical approach to a single incision [223], a few reports have revealed that surgical success might be diminished compared with perineal cuff placement and abdominal balloon reservoir placement [594, 595]. Henry and colleagues [596] noted in their retrospective analysis of patients treated with a perineal versus trans-scrotal AUS over a 17-year period (mean follow-up not given), the former group had a completely dry rate of only 28%, versus 57% in the perineal group (p<0.03). Beyond the difference in “completely dry” rate, social continence was also better in the perineal versus scrotal surgery (73% versus 60%). Thus the perineal approach for initial artificial urinary sphincter implantation appears to control male stress incontinence better than the trans-scrotal approach.

The trans-scrotal approach appears particularly useful for simultaneous placement of an AUS and inflatable penile prosthesis through a single incision, with Kendirci and colleagues [596] reporting a urethral erosion rate of 9%, an overall revision rate of 14%, and a social continence rate of 100% in 22 patients at 17 months average follow-up. Sellers, et al. [597] recommend the simultaneous surgery for cost-efficacy.
Figure 10: A. With the patient in lithotomy position, a perineal incision is made behind the scrotum to expose the bulbar urethra. B. The urethra is mobilized circumferentially within the bulbospongiosus muscle and the measuring tape is used to obtain the cuff size. C. The belt-like cuff is positioned around the urethra. 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. E. After reservoir insertion the cuff is pressurized with fluid. F. A scrotal space is created under the dartos and the pump is inserted (held with a Babcock clamp).
They demonstrated a $7,000 cost savings when both devices were implanted simultaneously through a scrotal approach, compared to staged implantation with 2 separate surgeries.

The trans-scrotal approach is also useful for revision surgery. Van der Horst and colleagues [598] described AUS revision through a trans-scrotal approach, with addition of a second cuff distal to the primary cuff. In addition, Comiter [166] described the trans-scrotal approach for placement of an AUS following previous perineal sling surgery. In the case of suboptimal continence following sling surgery, placing the AUS cuff distal to the sling through a scrotal incision allows the surgeon to avoid the previous operative field, minimizing dissection through potentially scarred tissue; secondly, it leaves the proximally placed sling as a partially effective compressive device proximal to the AUS cuff.

4. COMPLICATIONS

Complications following implantation of the AUS can be divided into the broad categories of incontinence, erosion and/or infection, and unusual complications. While the number of AUS procedures performed varies geographically throughout the world, especially within the United States. Certain “centers of excellence” perform substantially more procedures than do community hospitals [584]. However, 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 [206]. This suggests that erosion and infection may be more closely related to the physiologic state of the host rather than the experience of the surgical team, provided standard precautions are strictly applied.

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 [599-604]. 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 [599-610]. 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 [611]. The best candidates for sphincter implantation are those with a low pressure, relaxed, and compliant bladder but an incompetent urethral sphincter [608].

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 [237, 263, 611]. About 4 months following implantation, cuff efficiency diminishes, presumably because pressure atrophy occurs in every patient to some extent [612]. The incidence of urethral atrophy leading to revision varies from 3% to 9.3% [178, 184, 187, 586, 609, 613-615]. This atrophy can be lessened with nocturnal deactivation of the cuff [616].

3. MECHANICAL FAILURE
This includes perforation of one of the components with loss of fluid from 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% [613] to 52.5% [193] 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 [193]. In a recent publication from Baylor [187], chronicling a 13-year experience with the AUS, mechanical failure occurred at an average of 68.1 months postoperatively. 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 [617].

4. EROSION AND/OR INFECTION
Erosion and infection are two major complications that almost invariably necessitate removal of the prosthesis. Their incidence may be reported separately, or more commonly as a single complication. The incidence of these complications varies from 0% to 24.6% [178, 263, 586, 602, 608, 609, 613-615, 618, 619]. Most recent large series report an incidence of infection and erosion generally less than 8% [51, 186, 187, 198, 237, 611, 620, 621]. As would be expected, the highest incidence has been reported with the longest follow-up (10-15 years) [178]. Lai and colleagues [187] from Baylor recently reported that erosion occurred at an average of 19.8 months postoperatively rather than in the peri-operative period. Previous surgery [622] at the site of cuff placement increases the risk of erosion. This, however, may be decreased by delayed cuff activation [623]. 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 [624]. Other risk factors include urethral catheterization and urethral endoscopic manipulations with an activated sphincter in place [625].

A likely etiology of early erosion is intra-operative laceration of the urethra when dissecting it from the corpora cavernosa, where a difficult anatomical plane exists. Intraoperative recognition of urethral injury can be facilitated by retrograde perfusion sphincterometry using a flexible cystoscope [32]. While recognition of a urethral injury may alert the surgeon to the necessary termination of the procedure, urethral erosion may still occur without a known urethral laceration [626].

As mentioned above, while the majority of authors consider previous radiotherapy a risk factor for increased infection and erosion, it is not a contraindication to implantation of an AUS in the male patient with PPI [177, 179, 200, 236, 237, 260, 627]. Overall patient satisfaction is similar in those who have been irradiated, compared to those who have not been [177, 188, 236]. Furthermore, the degree of satisfaction does not diminish with an increased number of surgical revisions [192, 628].

5. 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 [629], or a giant urethral diverticulum at the site of a previously removed cuff because of erosion and urinary extravasation [630].

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 [609], the authors mention that the “mean operational life” of the sphincter was 56 months (range 3-118 months). Haab et al [184] 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 [190] 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. In that cohort, non-mechanical failure decreased from 17% to 9% and mechanical failure
decreased from 21% to 8% following introduction of the narrow back cuff [190]. 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 Lai's report regarding Baylor's recent 13-year experience with the AUS, only 6% of devices failed mechanically, at an average of 68.1 months, with 75% of patients requiring no revisions at 5 years [187]. In a review, Venn et al [263] 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 survival rate at 10 years was 66% in this series.

In a series of 30 boys with spina bifida Spiess et al [631] 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. In a series of 35 adolescents with neurogenic voiding dysfunction implanted with a bladder neck cuff over an 11-year period, with an average follow-up of 5.5 years, Lopez Pereira and colleagues [632] reported a 20% mechanical failure rate, with an additional 8.6% erosion rate. Adverse bladder storage changes developed in 31.8% of patients, who thereby required augmentation cystoplasty. However, continence was achieved in 91.4% of individuals. Ruiz and colleagues [633] followed 19 adolescents for an average of 80 months who were implanted with bladder neck cuffs over a 14 year period for reasons other than spina bifida. They reported a mechanical failure rate of 26.3%, an infection/erosion rate of 15.8%, and a revision rate of 26.3%. However, even in this very high risk group, a continence rate of 87% was achieved despite this high complication rate. 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. [183] 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 more than 72 months.

In other recent series, the global long term (2 to 7.7 years) revision rate, for any of the above mentioned reasons varies between 18% and 50% [186, 187, 191, 192, 628, 632-635]. In Webster's recent report [628] of 554 implantations over a 10 year period, (i.e. performed since the 1987 device modification), he noted a mechanical failure rate of only 31/554 (5.5%). Non-mechanical failure was 88/554 (15.9%), with 63/554 (11.3%) due to urethral atrophy and 21/554 (3.8%) due to cuff erosion. Of the total cohort, 21.4% required at least one revision surgery, while 78.6% did not. Of those 119 patients who required re-operation, 76.5% required no further treatment (similar to the non-reoperation rate of the initial cohort), while 23.5% required re-operation for either mechanical or non-mechanical failure. Five-year durability of the AUS following primary or secondary implantation was comparable, with 80% for the initial placement, and 88% following revision surgery. Similarly, continence status was comparable, with 90% of primary and 82% of revision patients achieving 0-1 pad per day urinary control. 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, 200, 206, 610, 636-638]. Figure 11 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 [639, 640] (Figure 1). Alternatively, sonography of the pressure regulating balloon may show volume loss. 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 2). Endoscopy will disclose any urethral erosion by the cuff (Figure 12).
Figure 11: Algorithm for managing incontinence after AUS placement
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 urethra 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) [606].

Intraoperative electrical testing, using an ohmmeter [619, 637] 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 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 188, 611. 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 [590]. However, in a recent review of 286 patients Furness et al. [641] demonstrated an infection rate of 14.5% and 6.8% with simultaneous and staged procedures, respectively. Catto, et al. [592] however, showed that while infections may occur earlier with simultaneous procedures, the ultimate infection rate is no different when augmentation cystoplasty and AUS placement separately or simultaneously. No clear urodynamic guidelines exist to select patients who need bladder augmentation in combination with an AUS [612], 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, 179, 642], 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 [196]. It should be mentioned, however, that there is a risk of reduced erectile function with this technique. The vast majority of such patients, however, already suffer from erectile dysfunction secondary to the prostate cancer surgery. Guralnick reported a retrospective chart review of 31 patients with an average of 17 months follow-up after trans-corporal cuff placement for varied indications (previous erosion, urethral atrophy, and radiation). The vast majority of patients (84%) realized 0-1 pad per day leakage post-operatively, with no device erosions or infections, while 3 patients (9.7%) required revision surgery for malfunction. Overall, 29 of 31 had erectile dysfunction prior to the procedure, and only 1 of 2 had deterioration of his erectile function post-operatively. Magera and Elliott [643] reported their results of 18 patients who underwent tandem cuff transcorporal salvage surgery. Ten patients had only the distal cuff placed transcorporally, while 18 had both cuffs placed transcorporally. Infection occurred in 1 patient (5.5%), and erosion occurred in 1 patient (5.5%), while 69% reported that they were very
improved or extremely improved with respect to continence at an average of 26 months follow-up. The implantation of a double-cuff AMS 800 has become more popular, as a primary procedure in the totally or severely incontinent patient [197, 644], or as a salvage procedure, by adding a second cuff, following a failed previous single cuff [194, 195, 644]. Dimarco’s group [195] and others have shown excellent results with the addition of a second urethral cuff, placed 1.5–2.0 cm distal to the primary cuff. Alternatively, a circumurethral wrap of an organic bulking agent can be fitted, with subsequent placement of the AUS cuff over the biologic external urethral bulking agent [645]. Early reports of primary double cuff placement did not demonstrate any significant increase in morbidity with the double-cuff as compared with the single cuff system [197], and patient satisfaction also seems to be higher [198] at an average of 21-41 months follow-up. However, with longer follow-up (58-74 months), the same group [199] reported that the complication rate was higher in men with primary double-cuff placement (55% versus 28%), and there were no significant differences in overall continence and QOL measures.

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 antibiotics. A second system can be subsequently implanted with equally good results [623]. 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% [646]. In 2007, AMS introduced the InhibiZone-coated artificial urinary sphincter (rifampin and minocycline hydrochloride coating) [643].

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 [629]. 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 2), 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 [647]. It is logical that intra-operative urethral injury may precipitate cuff erosion if unrecognized. However, Petrou and colleagues [628] showed that early postoperative cuff erosion can occur even when no laceration is demonstrated by intraoperative intraurethral instillation of indigo carmine.

8. CONSENSUS PROTOCOL FOR FOLLOW-UP OF PATIENTS WITH AUS
As complications continue to be seen for years after implantation [648], 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 [625].

2. Hospital stay should be kept to a minimum.

3. Urethral catheters, if inserted, 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 acceptable. Irradiated patients may benefit from a longer initial period of deactivation, up to 12 weeks [179]. Nocturnal deactivation should be considered in high-risk patients [178].

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 and monitoring of renal function 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 changes in the continence status occur, diagnostic procedures depicted in Figure 11 should be considered. (Level of evidence 3; Grade of recommendation B-C)
1. EVALUATION

Prior to surgery a basic patient evaluation should consist of history and physical examination, urinalysis and postvoid residual urine (Level of evidence 1-2: grade of recommendation A). A voiding diary is helpful to assess functional capacity and total urine output (Level of evidence 1-2: grade of recommendation B). Pad tests may be useful in certain circumstances (Level of evidence 1-2: grade of recommendation B). 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 (Level of evidence 2-3: grade of recommendation B). The committee felt that multichannel urodynamics are useful prior to invasive treatment for incontinence. (Level of evidence 3: grade of recommendation C)

2. INCONTINENCE POST-PROSTATECTOMY FOR BPO AND POST-RADICAL 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 with the longest record of safety and efficacy. Male slings are an alternative with intermediate data support their safety and efficacy in men with more moderate degrees of PPI, although long-term data are beginning to accumulate. However, the literature contains results on many different kinds of slings. Injectable agents are a less effective 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. Slings have variable results after radiation. 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 fistulas 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 AES 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 adjustable balloons is accruing and the early high complication rate appears to have been resolved. However, more evidence is required before specific recommendations can be made. (Level of evidence C; grade of recommendation D)

FUTURE RESEARCH DIRECTIONS

- New technologies, bulking agents, sling materials, prosthetic devices should continue to be evaluated
- Accuracy in reporting of early research results is mandatory
- Mechanisms of post-prostatectomy incontinence and device effects need further research

CLINICAL TRIAL RECOMMENDATIONS

- Randomized trials (AUS and slings)
- Standardized workup and outcome measures including QoL
- Complete reporting of complications and outcomes especially those of slings
- Reporting of procedures to salvage failures
- Long-term results (>2 years)
- Standardized reporting of durability

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