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# Development and Current Status of the AMS 800 Artificial Urinary Sphincter

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**Abstract**

The American Medical Systems (AMS) 800 artificial urinary sphincter (AUS) has developed into a sophisticated system for the treatment of patients with incontinence secondary to intrinsic sphincter deficiency. In this review article, we describe the development and mechanics of the device before considering the indications for its use. We present a comprehensive review of the recent literature concerning long term outcomes and complications of AUS implantation in various populations and also describe some of the newer techniques used in AUS implantation surgery.



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## 1. Introduction

Urinary incontinence is considered to be one of the most bothersome of all urological symptoms and its impact on quality of life cannot be underestimated. It is an underreported problem, and research into its causes and management has been limited due to a historical paucity of funding and resources. A large number of measures have been employed to treat incontinence resulting from sphincter deficiency over the years. These range from convenes, indwelling catheters and penile clamp devices to various surgical procedures involving reconstruction of the bladder neck and urethra. Although these procedures may be very successful, there are particular groups of patients in whom an alternative strategy is required, and implantation of an artificial urinary sphincter (AUS) is a technique which may be utilised under such circumstances. First introduced over 30 years ago, the device has continually evolved to its current, sophisticated form. It is widely used in clinical practice [1], and 100,000 devices have now been implanted worldwide. In this review article, the development of the AUS will be described, prior to a discussion of current clinical use of the device in paediatric and adult patients. Lastly, the most recent refinements and future strategies concerning the use of the device will be discussed.

## 2. AUS development

The concept of an AUS is not new. Indeed, it was first suggested by Foley in 1947 [2]. However, it was another 25 years before the introduction of the first commercially available AUS, the American Medical Systems (AMS) 721 [3]. This ingenious device comprised an inflatable cuff placed around the

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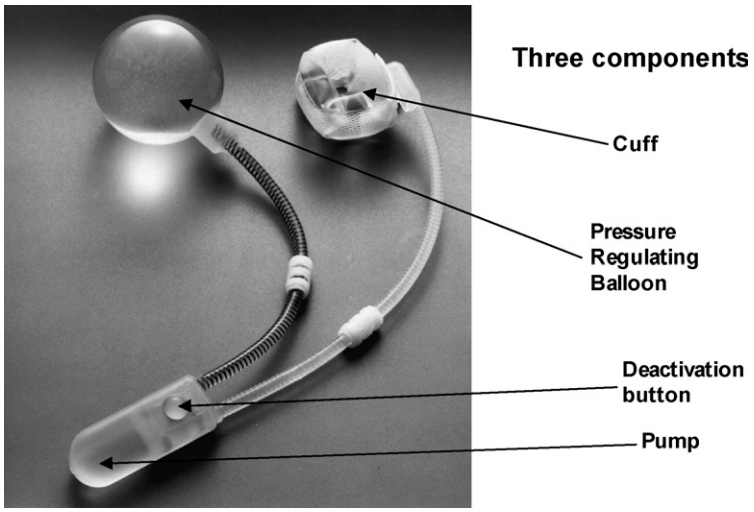


**Fig. 1 – The AMS components.**

bladder neck, a reservoir sited in the retropubic space and two pumps positioned in either side of the scrotum; one pump controlling inflation, and the other deflation of the cuff. The components were connected by piping and valves controlled the flow and pressure within the system. Although developments in material and technology subsequently occurred, the basic principles have remained the same. Early clinical experience with the original 721 device established that implantation of the large number of components and connecting tubing required extensive dissection and tunnelling, leading to frequent perioperative complications. The reliance on a number of spring-loaded valves led to an unacceptable rate of mechanical failure. The 1980s saw the evolution of the device which was developed in conjunction with the National Aeronautics and Space Agency (NASA) and led to the incorporation of high-technology aerospace-grade materials. A number of iterations of the device including models 743, 761, 791 and 792 were clinically used. The cumulative functional gains from years of refinement led to the development of the AMS 800, which is the model still currently in clinical use. The AMS 800 incorporates some ingenious features including a pressure regulating reservoir balloon, the incorporation of inflation and deflation into a single pump and kink-resistant tubing (Fig. 1). In addition, it is now possible to activate the AMS 800 several weeks after implantation, allowing tissues to heal around a full capacity pressure-regulating balloon, thus preventing contraction of the reservoir. The most recent refinements to the cuff were made in 1987, include surface treatment and change of shape to a narrow-backed design [4]. To aid assembly of the separate AUS components the kink-resistant tubing is colour-coded; black for balloon and clear for cuff. Tubing is connected by means of a straight or angled sutureless connector that requires special crimping pliers. Components of the AUS are filled either with isotonic radiological contrast or normal saline taking care to avoid introducing air bubbles or blood into the system. The former involves selecting a contrast media and diluting it with sterile water in a volume ratio advised by American Medical Systems. This allows the clinician to X-ray the AUS in case of malfunction. However, dilution errors can lead to device failure due to fluid leaving the balloon reservoir across an osmotic gradient thereby lowering the balloon and subsequently cuff pressure. Some clinicians therefore prefer to use normal saline to fill the device. Recently, with the increased usage of double cuff placement in men with severe post-prostatectomy incontinence AMS has developed a reliable sutureless Y-piece connector.

## 3. Mechanism of action

The degree of cuff occlusion is determined by the volume of fluid within the balloon reservoir and the thickness of the balloon wall. The latter is manufactured in 5 different sizes and due to the AUS pressure-volume relationship, filling a selected reservoir with between 16 and 24 ml of fluid, pressure within the device can be maintained within a pre-determined range (Table 1). AMS recommends using 22 ml of fluid for a single bulbar-urethral cuff device; some clinicians however use 25 ml in this situation and up to 28 ml for a double cuff. Cuff lengths vary from 4 to 11 cm to accommodate

**Table 1 – Components of the AUS**

| | |
|---|---|
| Occlusive Cuff | |
| Size (cm) | 4.0–7.5 (0.5 increments)<br>8.0–11.0 (whole increments) |
| Pressure Regulating Balloon | |
| 51–60 $cmH_2O$ | Traditionally used for patients with previous irradiation, but latest data shows higher pressure is acceptable |
| 61–70 $cmH_2O$ | Standard, most widely used pressure range |
| 71–80 $cmH_2O$ | Used with bladder neck cuff or occasionally on revisions for persistent incontinence |

urethral and bladder neck dimensions but all are 2 cm wide (Table 1). The most common components used in an AUS device placed around the bulbar urethra to treat post-prostatectomy incontinence are a 4 cm cuff and a 61–70 $cmH_2O$ balloon reservoir.

The central pump features a deactivation button, a valve and a refill delay resistor. When the AUS is active the cuff is full and continence is maintained. Repeated squeezing and releasing of the bulb of the pump empties both the cuff and the pump by unidirectional transfer of fluid to the reservoir. Refilling of the cuff automatically occurs, but does so slowly over about 2 minutes due to the presence of the delay refill resistor (Fig. 2a and b). If complete voiding is not achieved in this 2 minute period, the pump may be recycled. Transfer of the fluid between the 3 components of the AUS may be stopped by pressing the deactivation button. This is always done at the completion of AUS implantation and with the cuff semi-empty to allow urethral tissue healing. After 2–6 weeks the AUS is activated by sharply squeezing the bulb of the pump. This manoeuvre should be taught to every patient since early attempts at cycling the AUS may result in accidental deactivation of the device.

## 4. Indications

Implantation of an AUS device should be considered in those patients with intractable severe urinary

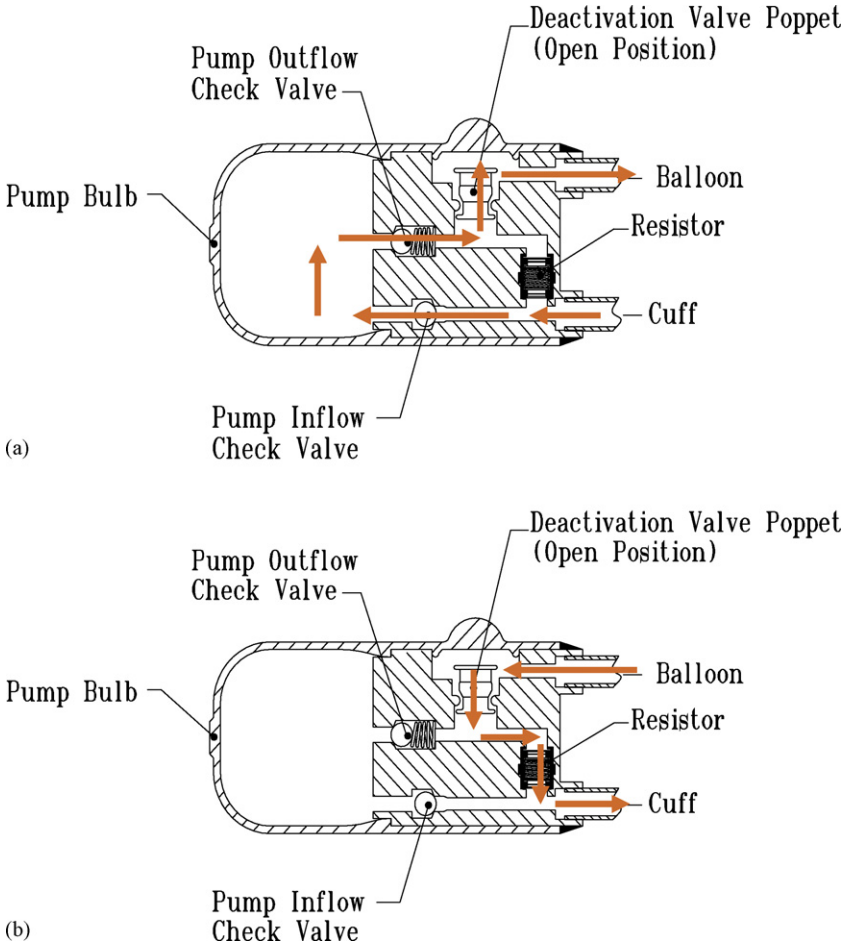


**Fig. 2 – (a) Schematic showing direction of flow of fluid from cuff to reservoir when the pump is cycled. (b) Schematic showing the direction of fluid as it returns to the cuff from the reservoir. Note the resister in the pump which ensures that filling takes place slowly.**

incontinence secondary to abnormally low urethral sphincter pressure. Prospective patients must demonstrate that they have the mental and physical dexterity needed to safely cycle the device and accept that revisional surgery over time is commonplace.

Over 90% of AUS usage is in adult males whose incontinence is secondary to radical prostatectomy Reported rates of this post-operative complication vary widely, but its effects on quality of life are considerable. Treatment options include Kegel exercise, peri-urethral injection of a bulking agent, a sling procedure or implantation of an AUS.

Neuropathic bladder dysfunction with intrinsic sphincter deficiency is an important indication for AUS placement in both adults and children. Detrusor hyperreflexia commonly coexists with intrinsic sphincter deficiency and may require treatment with an augmentation cystoplasty at the same time as AUS implantation to lower intravesical pressure and increase bladder capacity. Combining the two procedures has not been found to result in increased rates of prosthetic infection in the long term [5]. Severe urinary incontinence in children and adolescents is most commonly due to neuropathic bladder secondary to spina bifida. The artificial urinary sphincter certainly has a role in the management of these patients; the AUS cuff is usually placed around the bladder neck in the paediatric population.

The AUS has not found a definitive role in the management of incontinence in adult females, and its use tends to be limited to women with severe intrinsic sphincter deficiency in whom other approaches have failed [6]. Fortunately, there are a plethora of other effective anti-incontinence techniques that are employed primarily such as the tension-free vaginal tape, which has been shown to be safe, efficacious, technically simple to perform and is considerably cheaper than the AUS [7].

## 5. Preoperative and surgical considerations

Preoperatively, it is imperative to ensure that the patient has the manual dexterity and mental aptitude required to cycle the sphincter and that there is no lower abdominal, genital or perineal skin lesion(s) which might act as a septic focus. In general, a thorough preoperative work-up should always include urine culture, urodynamics and urethrocystoscopy. Other investigations may be tailored to suit each individual patient, so for example, all those with a neuropathic bladder must also have an appropriate upper tract evaluation. In post-prostatectomy incontinence, a urethrocystoscopy is important to exclude bladder neck stenosis. In our unit patients are admitted on the day of surgery, and are given an antiseptic chlorhexidine shower prior to transfer to the operating suite. Cefuroxime, metronidazole and gentamicin are administered at induction of anaesthesia and continued for 24 hours; it is important to cover prophylactically against prosthetic infection by gram positive or negative organisms as well as anaerobic ones. In penile prosthetic surgery the commonest prosthetic infection is due to *Staphylococcus epidermidis*. Other measures aimed at preventing infection are shown in Table 2.

**Table 2 – Minimising risk of prosthetic infection**

- Sterile MSU
- 10 minute betadine scrub
- Shave in theatre
- Water-proof drapes and gowns
- Double Gloving
- Minimise theatre traffic
- Laminar air flow tent
- Antibiotic irrigation
- Experienced implant surgeon
- Post-operative antibiotics
- Avoid haematomas

In men, the cuff may be placed around the bladder neck in those with neuropathic bladder dysfunction or around the bulbar urethra in those patients with post-prostatectomy incontinence in which case the cuff is typically placed after first reflecting the bulbospongiosus muscle. The pump is placed in a subdartos scrotal pouch. Traditional approach to sphincter placement in men requires two incisions; a perineal incision is made in order to place the cuff and a further suprapubic incision is made through which the pump and pressure regulating balloon may be sited. The pressure balloon may be placed either extra- or intra-peritoneally. In the early post-operative phase it is important to teach the patient to regularly pull caudally on the pump to prevent its upward migration which can make subsequent device cycling difficult.

In women, bladder neck placement of the cuff is achieved typically through a suprapubic, extraperitoneal incision but a combined transvaginal/abdominal approach maybe used when suprapubic adhesions are a problem. The pump is placed in the labium majorus via the suprapubic incision and the balloon placed in the retropubic space.

## 6. Results of AUS implantation

A large amount of data relating to continence rates, complications and patient satisfaction following

AUS implantation has accrued since the introduction of the device. Interpretation of these studies and direct comparison between them is confounded by interstudy variation in factors such as definitions of incontinence, surgical technique and patient selection and/or populations. To improve the outcomes of future AUS usage and indeed steer further development of the device we believe that national urological societies should conduct an annual prospective audit of the AUS using agreed definitions of incontinence severity and quality of life measures. Presented below is a summary of the results of the largest studies of AUS implantation in men, women and children.

## 7. Men

Urinary incontinence following radical prostatectomy may affect up to 60% of patients following surgery, although reported rates vary widely according to the definition of incontinence, surgical centre and the means of data collection [8]. The most widespread use of the AUS is in this patient population and a large number of series detailing continence and complication rates have been published. It is extremely difficult to compare these studies due to heterogeneous groups of patients, differing study protocols, and perhaps most importantly, inconsistencies in the definition of incontinence.

The largest reported series of 323 patients who received an AUS is from the Mayo Clinic [9]. This series includes 160 men who developed incontinence after radical prostatectomy, 40 patients suffering from incontinence following transurethral resection of the prostate and a further 26 who had received radiotherapy following radical prostatectomy. Mean follow up was 68.8 months. The continence rate was reported as 79% and 72% of patients did not require re-operation. The changes in cuff design in 1987 had a big impact on durability of the device with the five year survival of the pre-1987 device being 79% as opposed to 87.6% for the newer model. Mechanical failure occurred in 21% of the older devices and only 7.6% of the newer model, the rates of non-mechanical failure (infection or erosion) being 17% and 9% respectively. Interestingly, the group who had undergone prior pelvic radiotherapy had no significant difference in complications from those who had never been exposed to radiation. Anecdotally, other clinicians feel that previous radiation increases the risk of AUS revision to 50% at 5 years.

In a smaller series of 28 patients, Singh and Thomas [10] reported a ''social'' continence rate (defined as either complete continence or minor stress leakage) of 97% at mean 41 months follow-up. Of the 28 patients, 10 required revisional surgery, 6 of these for persistent stress leakage. Another small series of post-prostatectomy incontinence (part of a larger series of patients with incontinence of mixed aetiology) with a much longer follow up of 10 years was reported by Mundy [11]. This group of 23 men had a very impressive 10-year continence rate of 91%. However, 26% required revisional surgery in order to increase the pressure of the regulatory balloon. Presently, by using the new 4-cm cuff or double cuff technique at the initial surgery one may avoid having to use the higher pressure reservoirs for post-prostatectomy incontinence.

Litwiller et al. [12] assessed continence rates and patient satisfaction in a group of 50 men with post-prostatectomy incontinence. All of these men had severe incontinence with 70% requiring over 6 nappies a day. The patients were followed for a median of 23.4 months. Once again the continence rates after placement of an AUS were excellent with 20% completely dry, 55% leaking a few drops and 22% less than a teaspoon full of urine per day. A total of 90% of patients reported satisfaction with their AUS. This study differed from others in that the data was collected by means of a patient questionnaire as opposed to medical records and continence was strictly defined as no leakage. An important point highlighted by this study is that patient satisfaction does not depend on being completely dry post-operatively; instead the major determinant of satisfaction appears to be perceived improvement in continence.

A similar approach was taken by Gousse et al. in their series of 72 patients with post-prostatectomy incontinence and mean follow-up of over 7 years [13]. Their patients had considerable persistence of incontinence following AMS 800 implantation, 27% used no pads, 32% used 1 pad and 15% 1 to 3 pads per day. A significant 25% used more than 3 pads per day. Complication rates were consistent with other series, with mechanical failure occurring in 25%, erosion in 4% and infection in only 1 patient. Interestingly, 23% of patients reported being unsatisfied with the results of AUS implantation, contrasting sharply with the study by Litwiller [12]. The major difference between the two studies is the much longer follow up in the Gousse series, which suggests that problems encountered in the medium to long term take their toll on patient satisfaction.

It can be seen from the previous studies that the AMS 800 is certainly a very viable option for the management of post-prostatectomy incontinence.Indeed, overall the AUS achieved high rates

(77–97%) of continence in 496 patients and patient satisfaction was generally high. However, a significant overall rate of re-operation due to either mechanical failure or non-mechanical complications (erosion and infection) of 30% at a mean follow-up of 63.3 months is apparent. Thus, for less severe cases of incontinence, alternative strategies may be preferable.

Transurethral collagen injection is the least invasive method of surgically treating post-prostatectomy incontinence, and acts as a bulking agent. It can be injected by either an antegrade or retrograde approach [14]. In the largest reported series of 88 men who had undergone a mean of 3.5 collagen injections each, 47.7% of patients were rendered nearly completely dry [15]. Other studies have reported lower rates of complete continence [16,17], even after multiple injections. Using the antegrade approach to injecting collagen, Klutke et al. reported an improvement rate of 45% at 28 months in 20 patients [18]. Macroplastique is another material which has been used as a urethral bulking agent. A study by Imamoglu et al. showed that it was equally as effective as AUS implantation in men with mild post-prostatectomy incontinence, but was inferior to the AUS in those with severe incontinence [19]. It is evident that the AMS 800 confers far superior cure rates in the medium-long term and therefore is the procedure of choice in those with severe post-prostatectomy incontinence. In those with milder incontinence, collagen or macroplastique injections or the new InVance™ procedure (described below) maybe acceptable alternatives.

## 8. Women

The largest reported series of AUS implantation in women is that of Costa et al. [20] who followed 207 women with intrinsic sphincter deficiency (ISD) of various aetiologies. The sphincter was implanted using a modified abdominal approach, the cuff being placed around the bladder neck between the periurethral fascia and vagina. The reported rate of continence was 88.7% and 81.8% in those with non-neurogenic and neurogenic bladders respectively. A total of 12 devices were removed due to erosion or extrusion. The only risk factor for device removal was perioperative urethral injury. An earlier study in a much smaller group of 25 patients with ISD secondary to multiple failed cystourethropexies also showed an extremely high rate of continence of over 90% after 2.5 years follow-up.

Although the abdominal approach has been widely supported, scarring secondary to previous bladder neck surgery may make this technically challenging. Appell reported a series of 34 women in whom he implanted the AUS using a vaginal approach; the pressure regulating balloon was placed supra-pubically and extraperitoneally and the pump placed in the labium majorum through a separate suprapubic incision. The reported success rate was 100% with no increased risk of erosion or infection compared to the abdominal approach [21]. The development of the minimally invasive mid urethral sling in the mid 1990s by Ulmsten and Petros effectively signalled the demise of the AUS as a primary treatment for intrinsic sphincter deficiency in women. However, it remains a very effective option for women who remain incontinent after other failed procedures. A history of pelvic radiotherapy is an absolute contraindication to placement of AUS in women [22].

## 9. Children

A number of studies have investigated the use of AUS devices in children [23–30] with particular reference to its durability, continence and complication rates, and subsequent surgical procedures which may be required.

The largest reported case series in children is that of Rink et al. [30]. These investigators studied a total of 142 patients who underwent implantation of an AUS between 1980 and 2002, of whom 134 were available for analysis (93 males and 41 females). Of these, 59 patients initially received a pre-AMS 800 model (742/792) and the remaining 75 received an AMS 800. The median age of the patients at time of implantation was 10 years, and the most common indications for use were neuropathic bladder secondary to myelomeningocoele or sacral agenesis, and the exstrophy/epispadias complex. The mean period of follow-up was 6.9 years for the pre-800 models and 7.5 years for the 800 model. Following sphincter placement, 30 patients had to have permanent removal of the sphincter, primarily due to urethral erosion or infection. However, of the remaining 104 patients, the continence rate was excellent (92%). Spontaneous voiding was achieved in 22% of patients and a further 11% voided in conjunction with intermittent self-catheterisation (ISC), the rest of the patients requiring ISC via the urethra (48%) or via a catheterisable channel (16%). Only 3% of patients subsequently required a urinary diversion procedure. Rather predictably, mechanical complications were commoner in pre-800 models (one complication every 7.6 years), than in the AMS 800 (one complication every 16 years) and

33 patients required replacement of a pre-800 device with an AMS 800. The authors found that 28% of patients required bladder augmentation following AUS implantation, and that pre-operative urodynamic data did not accurately predict the likelihood of the patient requiring augmentation.

Three other studies also have a follow-up of more than 5 years [28,29,31]. Levesque et al. [28] reported 10-year follow-up in a series of 54 patients in whom a sphincter was placed between 1978 and 1990. This series was further subdivided into those who received a sphincter pre-1985 (36 patients) and those who had an AMS 800 placed between 1985 and 1990. Of those patients with sphincters still in place, continence rate was 82% and 36% void independently. The rate of post-operative bladder augmentation was 37%. Interestingly, there was no statistical difference in the probability of sphincters surviving for 10 years between the pre- and post-1985 groups, the figure being approximately 70% in both. Kryger [29] reported an extremely long 15-year mean follow-up in a series of 47 patients with predominantly neuropathic bladders, of which data were available for 32. A total of 19 patients retained their sphincter, 13 having been removed due to infection or erosion. Continence rates in those who retained their sphincter were extremely high (18 out of 19 patients) and overall continence rate was 56%. Volitional voiding was possible in 7 out of 19 patients, and 7 patients required subsequent bladder augmentation. A total of 33 AUS revision procedures were required. Gonzalez reported a small series of AUS implantations in 19 boys with neuropathic bladders with a mean of 8 years of follow up [31], the continence rate being 84%, and 25% of patients voiding spontaneously. Bladder augmentation was required in 39%.

The AUS has thus been shown to be an effective procedure in children, especially in those with neuropathic bladders. The most common indications for removal, and thus failure of the procedure, are erosion and infection. Risk factors which may predispose to these complications are previous bladder neck surgery, previous AUS erosion and a balloon pressure of more than 70 $cmH_2O$, but all of these factors have never been shown to be statistically significant [24,29,30]. Interestingly, data from the largest series [30] demonstrated a highly significant incidence of erosion when the cuff was placed on a segment of bowel used to create a neourethra.

The importance of preoperative urodynamic assessment of children is emphasised in all the studies described above. As noted above, detrusor overactivity, low bladder compliance and small bladder capacity may require correction by means of ileocystoplasty prior to AUS implantation. Alternatively, both procedures may be safely performed at the same time, providing careful operative technique is observed [32].

Some authors suggest that careful urodynamic assessment also allows prediction of future need for bladder augmentation following AUS implantation [33], whilst other investigators dispute this [34]. This unpredictability along with a well-defined incidence of detrusor overactivity following AUS implantation [35–37] requires careful post-operative urodynamic follow-up if upper tract damage is to be avoided. Normal upper tract function is considered essential prior to AUS implantation and this may necessitate correction of abnormalities such as vesico-ureteric reflux (VUR) [38].

## 10. Troubleshooting

It can be seen that although the results of AUS implantation are generally excellent, the device is not ideal. There is a group of patients in whom AUS implantation fails to achieve continence and another significant group who experience mechanical or non-mechanical complications. The most common presenting symptom of AUS dysfunction is persistent or recurrent incontinence, which may be the result of initial technical error in component selection, detrusor overactivity, mechanical failure of device components, or non-mechanical causes such as urethral atrophy and cuff erosion. It is mandatory to investigate all causes of recurrent incontinence. We perform urethroscopy to exclude cuff erosion, urodynamics to exclude the development of detrusor instability and radiological imaging with the cuff full and empty to ascertain fluid leakage from the AUS.

Perhaps the most devastating complications following AUS implantation are device infection and erosion. Infection necessitates removal of the device and delayed reimplantation. The confirmation of asepsis is vital prior to a secondary procedure. Urethral cuff erosion also requires removal of all components and delayed reimplantation if possible. Cuff erosion may occur early or late. Whilst the former may be due to iatrogenic causes at implantation or infection, it seems likely that late erosion is due to cuff pressure resulting in urethral damage;in some cases it occurs after inappropriate urethral catheterisation.

Mechanical device failure is estimated to occur in 7.6-21% of patients [39], although it is likely that over a very long time period, the rate of mechanical

failure will be higher. Indeed, the life expectancy of the AMS 800 is 10 years. The most common cause of mechanical failure is leakage of fluid from the system, the cuff being the most common site at which this occurs. The cuff is also the most common single component to fail. If mechanical failures occur early, the single component at fault may be replaced. However, if the AUS has been *in situ* for a number of years, it is better to replace the whole device due to the high probability of other aged components subsequently failing.

Urethral atrophy may occur due to chronic compression and is a frequently observed phenomenon, usually presenting as recurrent incontinence after initial successful AUS placement. Urethroscopy usually reveals the cardinal finding of poor urethral coaptation. This complication usually requires reoperation and component or device replacement. A number of approaches to cuff replacement have been described. Downsizing the cuff to a minimum of 4cm is a strategy that can be used if the urethra appears healthy and a large cuff was originally used. Alternatively, the cuff may be moved proximally along the urethra. If these measures are impossible, the cuff may be placed transcorporally, which adds bulk to the urethra to allow better cuff sizing whilst reducing the risks of future erosion and intra-operative urethral injury [40]. Another option for the treatment of sub-cuff urethral atrophy is the combined placement of an external bulking agent which increases the urethral circumference allowing standard cuff placement. This combined procedure was shown to be effective in a small series reported recently [41].

In men with severe recurrent incontinence, it is possible to incorporate a second cuff placed around the distal urethra in an attempt to improve results. This ''double-cuffing'' technique was first reported in 1993 in a study which showed that 80% of men who were still significantly wet after the placement of one cuff were treated satisfactorily by the placement of an additional cuff [42]. The long-term follow up data on this group of patients was published [43] and of 85 patients with double cuffs, over 97% of them remained dry. The rate of cuff erosion was approximately 10% and rate of infection was necessitating removal of the device was 1%. Double cuffs may also be implanted as a primary procedure in men with severe incontinence. A retrospective case control study of 56 men with post-prostatectomy incontinence who underwent implantation of either single or double cuffs also favoured the latter [44]. There was a significant increase in rate of complete continence (no pads required) and quality of life (measured using the incontinence impact questionnaire short form) in the double cuff group compared to the single cuff group. Rates of complications in both groups were equivalent.

## 11. New developments

As described above, the traditional approach to sphincter implantation in adult males involves two incisions. More recently, a single high trans-scrotal approach has been advocated [45], the benefits of this approach being ease of scrotal pump placement and excellent access to the bulbar urethra. In their small series of 37 patients who underwent placement of the AUS via this approach, Wilson et al. report complete continence rates of 66% with no increased incidence of complications compared to the standard approach. Placement of the pressure regulating balloon in the retropubic space when using the trans-scrotal technique may be difficult as it requires blind piercing of the transversalis fascia. An alternative, ectopic placement of the balloon anterior to the transversalis fascia but beneath the abdominal muscles has been shown to be a safe and effective procedure [46]. This novel single scrotal incision technique is quicker than the standard approach, and offers the potential advantage of simultaneous placement of an inflatable penile prosthesis in those unfortunate patients rendered both impotent and incontinent following radical prostatectomy. This is referred to as the AMS1500 procedure, comprising dual placement of the AMS800 AUS along with the AMS700 inflatable penile prosthesis. A recent study showed that the AMS 1500 procedure was cost-effective and took less time than implanting both prostheses separately [47]. However, if early infection occurs with the AMS 1500 procedure both devices may need to be removed. It is important that the surgical outcomes of the high scrotal incision for AUS placement in post-prostatectomy incontinence continues to be carefully reviewed as this approach may site the cuff more distally on the urethra than does the standard perineal incision, with the implication that continence rates may be compromised.

In order to address some of the shortcomings of the AMS 800 device, Mundy et al. have developed a proprietary AUS [22]. The cuff of the new sphincter is moulded from a curved template which is thought to reduce cracking of the cuff. The design also incorporates a second pressure-regulating balloon which rapidly increases cuff pressure in response to increasing intra-abdominal pressure, which ultimately should lead to a lower rate of post-implantation stress leakage. The overall pressure in the

system is lower than that found in the AMS 800, the putative advantage being lower risk of urethral erosion. Long term results are awaited.

Until recently, injection of peri-urethral bulking collagen or macroplastique and AUS implantation were regarded as the sole surgical treatments for male incontinence secondary to intrinsic sphincter deficiency. A novel approach using a bone-anchored synthetic suburethral sling has been developed (InVance TM, male sling system, AMS). The principle of bulbo-urethral compression by means of a perineal sling is not new, but early attempts at this technique were fraught with complications including perineal pain, fistulae formation [48], and required an abdominal incision to anchor the sling to abdominal fascia. The new InVance TM system employs six titanium bone anchors which are placed into the inferior pubic rami. Sutures attached to these anchors hold the sling in place. The advantages of the perineal sling over the AUS are that cycling of the device via a scrotal pump is avoided, and that there is no circumferential urethral compression, reducing the risk of erosion. Furthermore, with the sling being a simple device, the incidence of mechanical malfunction is likely to be significantly reduced. Finally,the list price of the male InVance TM sling system is £2,163 plus VAT compared to £3,693 plus VAT for the AUS device.

Several groups have reported early to intermediate results of this male perineal sling procedure in cases of post-prostatectomy incontinence. A series of 48 patients reported by Comiter shows that 80% of men with pre-operative severe incontinence (>3 pads/day) are either completely dry or wear 1 pad per day at a median follow-up of 48 months following sling procedure [49]. Less encouraging results were observed by Castle et al. in their series of 42 patients. They only achieved success, defined as usage of less than 1 pad/day or social continence in 39.5% of patients [50]. They also observed that if the patients were stratified in terms of pre-operative severity of incontinence, the group of men with mild-moderate incontinence did better with a sling than those with severe incontinence. Thus, while the AUS is likely to remain the gold standard for treatment of severe incontinence, the male sling may find its niche in the treatment of mild-moderate incontinence.

Infection rates of penile prostheses have fallen significantly (to about 1% in the virgin, non-diabetic patient) due to a number of measures the latest being the development of prostheses coated with a hydrophilic layer containing antibiotics [51]. If the same coating process is applicable to the AUS similar benefits might be seen.

A recent audit of AUS implantation in the UK [52] showed that 67 surgeons placed 677 sphincters (391 primary and 286 revisions) between 1999–2003 .Just 24 AUS devices were placed in children. Only 9% of surgeons implanted more than 10 AUS devices over this period and 72% of surgeons implanted one or less AUS devices for each year of the audit period. Reasons for revision in 186 cases were mechanical problems (in 65 patients), erosion (31 patients), infection (31 patients) and recurrent incontinence (59 patients). It seems reasonable to suggest that in order to improve outcomes, the use of the AUS should be limited to centres with extensive experience with the device. Indeed, one might even argue for the existence of the supra-regional prosthetic urologist who would be trained to implant both penile prostheses and the AUS.

## 12. Conclusions

The current commercially available AMS 800 is a sophisticated device that has attained high levels of efficacy and reliability following years of continuous development. A large number of studies reviewed herein have found the AUS device to be safe and well tolerated in various patient sub-groups. However, the device is not perfect; revision rates are commonplace at 10 year follow-up, patient satisfaction does not necessarily equate with being completely dry and the cost of the device is high.

The device is primarily indicated in severe post-prostatectomy incontinence (over 90% of AUS usage) and neuropathic bladder dysfunction in the paediatric and adult population.

Conclusive evidence that a double cuff is better than a single cuff for severe post-prostatectomy incontinence is lacking and a prospective randomised trial on this issue would be helpful. Similarly, the continence rates of the high scrotal incision for placement of the AUS compared to the standard perineal approach need further evaluation.

The literature does not support the use of the AUS as a primary treatment for intrinsic sphincter deficiency in women and it should be avoided as a salvage procedure in women if there has been previous pelvic radiotherapy.

Whenever use of the AUS is considered, patient selection must be rigorous and detailed pre-operative counselling is essential as is life-long follow-up.

In order to achieve the best outcomes AUS usage should be limited to centres with significant experience of the device and in the future this might fall within the remit of a supra-regional prosthetic urologist; that is a urologist with a tertiary

referral practice who implants both penile prostheses and the AUS. Annual audit of AUS implantations, using agreed definitions of incontinence and quality of life measures, should be a goal of every national urological society.

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## CME questions

Please visit www.uroweb.org/updateseries to answer these CME questions on-line. The CME credits will then be attributed automatically.

1. Which of the following statements about the AMS 800 artificial urinary sphincter (AUS) are true?
   (a) The 51–60 cm $H_2O$ pressure regulating balloon is used most commonly.
   (b) The 3.5 cm cuff is the smallest size available
   (c) All cuffs have a width of 2 cm.
   (d) Radiological contrast media diluted with sterile water may be used to fill the device.
   (e) Underwent significant refinements to its cuff design in 1987.

2. The AUS device may be implanted:
   (a) Through a single low scrotal incision.
   (b) At the same time as a penile prosthesis.
   (c) As a salvage procedure in women with intrinsic sphincter deficiency.
   (d) At the same time as performing an ileocystoplasty.
   (e) In the presence of a UTI.

3. AUS outcomes include:
   (a) High rates of continence exceeding 70% and high patient satisfaction.
   (b) A re-operation rate of about 25% at 5 years.
   (c) A lower re-operation rate for the post-1987 device.
   (d) Persistent incontinence due to inappropriate cuff sizing.
   (e) Recurrent incontinence from cuff erosion.

4. Preoperative considerations require:
   (a) An assessment of the patients manual and mental dexterity.

(b) A negative urine culture.
(c) Isotope renography in all cases.
(d) Ambulatory urodynamic assessment.
(e) An intravenous urogram.

5. Recurrent incontinence with an AUS in post-prostatectomy patients:
   (a) Is nearly always due to a reservoir balloon problem.
   (b) May show poor urethral coaption at urethroscopy.
   (c) May respond to cuff down sizing.
   (d) May respond to moving the cuff distally along the urethra.
   (e) Can be treated by placing the cuff in a transcorporal position.