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·*Clinical Experience*·

Combination therapy for male erectile dysfunction and urinary incontinence

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Abstract

Urinary incontinence (UI) and erectile dysfunction (ED) are both very prevalent conditions. Insertion of an artificial urinary sphincter (AUS) and penile prosthesis (PP) is an effective and proven method of treatment for both conditions. With advancing age, as well as with increasing populations of patients radically treated for prostate cancer, the occurrence of both conditions found in the same patient is increasing. The purpose of this article was to analyze the available evidence for simultaneous surgical management of male ED and UI using prosthetic devices. The existing literature pertaining to dual implantation of AUS and PP was reviewed. The concomitant insertion of the PP with the male perineal sling was also considered. Concurrent ED and UI are increasingly seen in the post radical prostatectomy population, who are often younger and less willing to suffer with these conditions. Insertion of an AUS and PP, either simultaneously or as a two-stage procedure, appears to be a safe, efficacious and long-lasting method of treatment. The improvements in design of both the AUS and PP as well as the development of the single transverse scrotal incision have made simultaneous insertion of these prostheses possible. Dual implantation of the PP and male sling looks promising in a selected population. In conclusion, the insertion of the AUS and PP for the treatment of concurrent UI and ED is safe and effective. Simultaneous insertion of these prostheses in the same patient offers potential advantages in operative and recovery time and is associated with high patient satisfaction. Combination therapy should therefore be included in the arsenal of treatment of these conditions. *(Asian J Androl 2008 Jan; 10: 149–154)*

Keywords: urinary incontinence; erectile dysfunction; impotence; penile prosthesis; artificial urinary sphincter; male sling

1 Introduction

Urinary incontinence (UI) due to urethral sphincter dysfunction affects up to 40% of men who have undergone radical prostatectomy [1]. The artificial urinary sphincter (AUS) is recognized as the gold standard for the treatment of urethral sphincter dysfunction and is also indicated in patients following urethral trauma where other anti-incontinence measures have failed. Erectile dysfunction (ED) affects an enormous number of men, most of whom have an organic cause for their ED. When conservative measures have failed to successfully treat ED, the insertion of a penile prosthesis (PP) is a well established option with excellent long-term results and a consistently high patient satisfaction rate.

In a significant number of men, ED and UI co-exist, understandably contributing to a significant decline in quality of life. In addition, the numbers of men undergoing radical treatment for relatively early stage prostate cancer is increasing, leading to a growing population of men with concurrent organic ED and urethral sphincter incompetence. Although most of these patients can be adequately treated with conservative treatment modalities, approximately 2% will elect to have a PP inserted [2] and a higher proportion to have an AUS inserted. Synchronous or non-synchronous insertion of an AUS and PP is an appropriate treatment option in these patients, with good long-term results.

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2 Historical perspective

The modern versions of both the AUS and the PP were popularized by Scott in the 1970s [3, 4]. Since then, there have been progressive improvements in the design of both implants. In 1983, the AMS 800 was introduced. This version of the device consisted of a narrow-backed cuff coated with a special lubricant, which allowed for a more even distribution of pressure around the cuff and a reduction in kink and stress fatigue, which can cause leakage. It also resulted in a significant reduction of urethral atrophy [5]. Other developments included the introduction of a poppet valve in the pump which facilitates deactivation of the device and kink-resistant tubing with improved connectors. These developments, together with delayed activation of the device after insertion, have dramatically reduced the risks of complications [5].

The penile prosthesis can be inflatable, with two or three-piece types, or semi-rigid, which include the malleable and mechanical types. They are indicated in a variety of conditions which cause ED, such as Peyronie's disease, corporal fibrosis following priapism, ED following radical treatment for prostate cancer, spinal cord injury and in those patients requiring penile reconstruction following penile girth or length loss. Refinements of the PP such as Teflon sleeves on the cylinders have greatly improved the longevity and satisfaction associated with this device.

Synchronous insertion of the AUS and PP has not become popular despite obvious advantages. The reasons for concern are problems with mechanical failure associated with each device and the risk of infection, which would potentially necessitate the removal of all components. In addition, there were concerns over the extent of dissection required to insert and place the components, further increasing the risks of erosion and infection.

A two-stage procedure implies that extra care is needed to avoid damaging the components of the existing implant and the added danger of operating in an area with surgical scarring. With the development of the single transverse scrotal incision to insert an AUS [6], the synchronous insertion of an AUS and PP became possible. The advantages of this approach are a single incision and anaesthetic, faster operating time, shorter hospital stay and possibly the supine position, which allows more mobility of the bulbar urethra. The pump of the AUS is also easier to place and may reduce the risk of pump migration [6].

3 Assessment of patients

A detailed history and examination of the patient assists in identifying the etiology of the ED and urinary incontinence. Video urodynamics are required to verify sphincter incompetence, supplemented by cystoscopic examination of the urethra and bladder neck regions, a voiding diary and a pad test. In most cases of organic ED, the cause is obvious in this population, such as a history of radical prostatectomy for prostate cancer. However, if there is some doubt as to the diagnosis of ED, a full ED work-up should be performed, including nocturnal penile tumescence studies and Doppler studies were appropriate.

The patient should possess the intellectual capacity and manual dexterity which would allow them to use the devices correctly. Any detrusor overactivity, especially in the context of a small capacity bladder should be treated prior to implantation of an AUS.

4 Surgical technique

Careful preoperative preparation of the patient is critical to reducing the incidence of infection. It is important to exclude any urinary tract infection prior to insertion of the penile and artificial sphincter prostheses. Additionally, care should be taken that there is no irritation in the perineal or genital skin. If a Foley catheter has been in place, this should be removed a week or so prior to surgery to eradicate bacterial colonization urine. Some surgeons recommend that the patient use a chlorhexidine-based wash 24 hours before surgery to reduce the overall bacterial load on the skin. Following induction of anaesthesia, the patient is placed in the supine position with the legs slightly abducted. He should be shaved in the operating room, just prior to surgery, to minimize abrasion and trauma to the perineal skin which can also increase the risk of infection. A 5- to 10-minute scrub of the perineal and suprapubic skin with chlorohexidine soap, followed by application of alcohol-based disinfectant reduces intraoperative colonization.

Although the use of antibiotics associated with the AUS and PP vary widely, the use of preoperative antibiotics is universal. Antibiotics should be broad-spectrum and cover both aerobic and anaerobic organisms and should be given parenterally. They should be continued in this fashion for 24 hours, after which they may be given orally, usually for further four or five days.

A soft latex 12–14 Fr Foley catheter is placed in the urethra. To insert both the PP and the AUS, a single transverse scrotal incision is made a few centimeters below the penoscrotal junction [7] (Figure 1A and 1B). This incision allows adequate exposure to both the bulbar urethra and the corpora. The corpora are then exposed and the scrotal septum is divided. The bulbocavernosus is dissected to expose the entire bulbous urethra and the remainder of the bulb is dissected free from the corpora by dissecting through the Buck's fascia. Wilson [6] reports that by using the single upper transverse scrotal incision, the bulbocavernosus muscle does not

need to be disturbed in order to place the AUS cuff at the bulb. However, to access the proximal bulb, the muscle must be retracted ventrally while continuing to divide the midline attachment to the raphe. This dissection should be continued until the perineal body has been encountered and divided sharply. Circumferential dissection of the urethra is then performed for a sufficient vertical distance to accommodate the 2.0 cuff width. The correct AUS cuff size is then determined using the measuring device and the cuff placed. In most cases, the remaining elements of the AUS are placed prior to starting the PP part of the surgery.

Vertical corporotomies are then made bilaterally (Figure 2). The corpora are dilated and sized for the cylinders (Figure 3). Once the cylinders are in place, the corporotomies are sutured such that they are water-tight. The bladder is then emptied by suction and the catheter plug or clamp replaced. Gloves and suction tip are changed. The reservoirs are then placed on either side in the prevesical space by puncturing the transversalis fascia [7] and the tubing, pump and connections are completed. The pumps are placed in the scrotum on either side, without opening the tunica vaginalis (Figure 4A and 4B)**.** The AUS is cycled and left in a deactivated state and the PP is left inflated overnight as usual to minimize bleeding. A Foley catheter is left in place for 24 hours**.** A suction drain may be placed at the lowest point of scrotal dissection, coming out at the level of the pubic tubercle (Figure 5A and 5B). Layers are closed by continuous suture, with care not to damage any prosthetic material. Usually three layers can be closed before skin closure and dressing is applied.

Some surgeons use a second low transverse suprapubic incision to place the reservoir of the PP [8]. However, access can usually be accomplished via the scrotal approach and thus both implants can be successfully placed with a single scrotal incision. Important maneuvers to help avoid infection post operatively include meticulous care and avoidance of hematoma formation. Some surgeons will also apply ice packs to the perineal area to reduce edema and assist with pain control [8].

If the implants are not to be placed synchronously, the AUS is usually placed first followed by the PP. Great care needs to be taken to avoid interrupting the AUS cuff when subsequently placing the PP components, especially the cylinders. A malleable prosthesis can also be inserted via the penoscrotal transverse incision and dissection of the corpora more distally can avoid encountering the AUS prosthesis. An added advantage of using a malleable prosthesis is the smaller number of components needed, especially if the scrotum is small.

Patients can usually be discharged within 24 of surgery on oral antibiotics. The inflatable PP can be activated in as early as 2 weeks, if intracorporal fibrosis was marked; otherwise cycling can begin at 6 weeks when the AUS can also be activated.

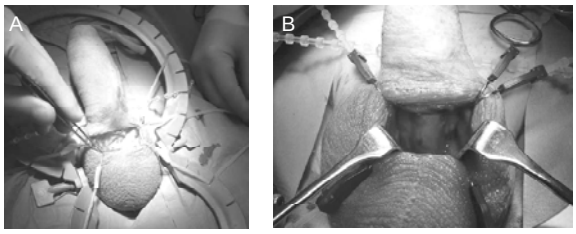

Figure 1. (A): The Lonestar retractor is used to help achieve adequate exposure. (B): A single scrotal incision is made for insertion of both the penile prosthesis (PP) and the artificial urinary sphincter. The bulbocavernosus muscle can be seen with the corporal bodies on either side.

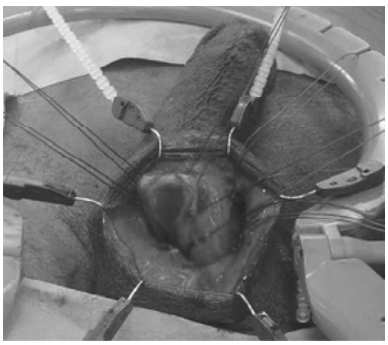

Figure 2. Vertical corporotomy for insertion of the penile prosthesis (PP). Horizontal incisions can lead to nerve damage and should be avoided.

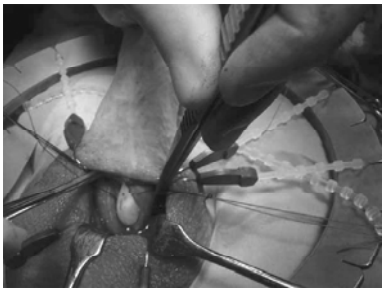

Figure 3. Vertical corporotomy with a malleable prosthesis in place. Closure of the corporotomy should be watertight.

The male perineal sling is a procedure which is more recently gaining popularity for the treatment of male UI. It uses a silicone coated polymer mesh material and is anchored in place by 6 bone screws which are fixed to the descending pelvic pubic rami, resulting in compression of the distal bulbar urethra by increasing urethral coaptation at this point. The operation has previously been described in the literature and essentially consists of a mid-perineal incision and exposure of the bulbos-

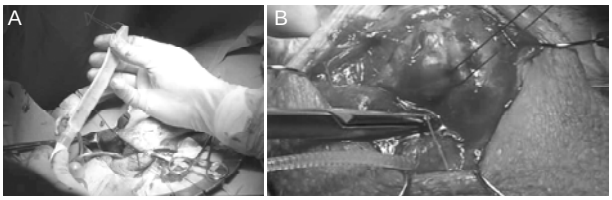

Figure 4. (A): One penile cylinder is in place and the other cylinder is about to be placed. The reservoir can be seen with the connecter tubing attached to the cylinders. (B): Both penile cylinders are in position with the tubing coming proximally. The corporotomy is being sutured ensuring that the closure is water-tight.

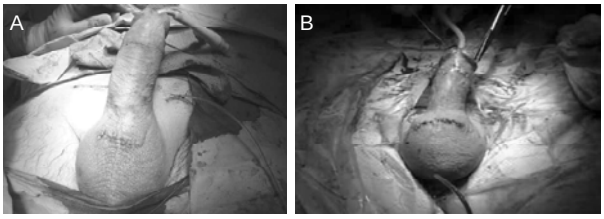

Figure 5. Final immediate post-operative appearance of synchronous insertion of penile prosthesis (PP) and artificial urinary sphincter. (A): In this case, two incisions were made; a scrotal incision to place the sphincter and a suprapubic incision to aide in the placement of the penile prosthesis components. (B): Synchronous insertion of PP and AUS using a single scrotal incision: immediate post operative appearance.

pongiosis muscle, The material is anchored to the inferior public rami utilizing titanium bone screws.

Broad-spectrum antibiotics are given and the patient is placed in an exaggerated lithotomy position. Under general or spinal anesthesia, a 16-Fr Foley catheter is placed. A midline perineal incision is then performed with dissection down to the bulbospongiosus and inferior pubic rami (Figure 6). Six titanium screws–three on each side–with swedged on #1 polypropylene sutures are then drilled in the pelvic bone, carefully avoiding the corpora as there is a risk of bleeding. The perineal incision may be shifted superiorly or a separate penoscrotal incision is made to facilitate the insertion of the PP. The cylinders of the inflatable PP are inserted next via corporotomies as usual. The remaining components of the PP are placed but left deflated so that the mesh of the sling can be positioned more easily and to prevent damage to the components of the PP (Figure 7A and 7B). The polypropylene mesh is then tied down on either side using the sutures already attached to the screws and the tension is adjusted**.** A retrograde leak point pressure test may be performed at this point. The sutures are then tied. There should be some resistance to passing the 16 Fr Foley after the sling is placed. In a small series of patients who underwent this procedure, there were no perioperative complications and all were home within 24 hours. All

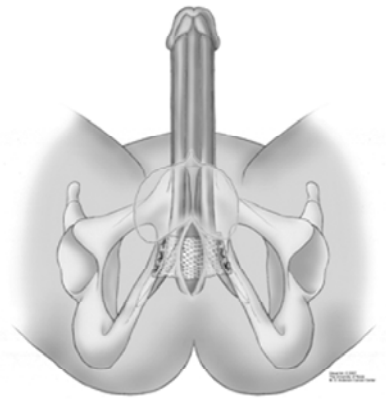

Figure 6. Midline perineal incision for the placement of the male perineal sling.

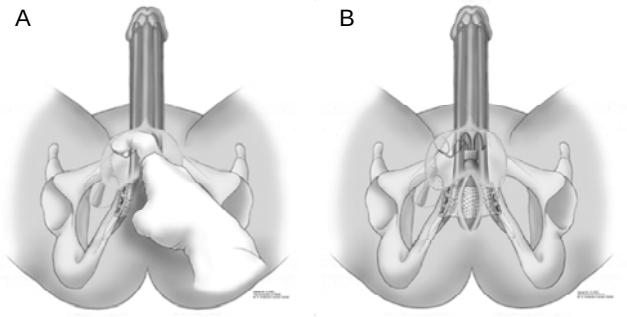

Figure 7. (A): The cylinders of penile prosthesis (PP) are implanted. The fascia transversalis at the right external inguinal ring is approached through the same perineal incision and perforated medial to the spermatic cord. A pouch in the space of Retzius is developed with index finger for the placement of reservoir. (B): All components of the penile prosthesis (PP) and male sling are in place. The prosthsesis is cycled and the pump is left in a dartos pouch in a dependant position.

patients were completely dry and satisfied at one year [9]. Alternatively, the sling may be placed in its entirety followed by the PP. However, due to the placement of the apical screws close to the pubis, it may then be difficult to insert the PP [9].

5 Complications

Although there is much written about the outcomes of AUS and PP insertion alone, there is a relative paucity of quality data involving the outcome of synchronous insertion of AUS and PP. Most studies mention the combined procedure anecdotally within series looking at either device alone. These represent very small numbers, about which it is difficult to comment. However, two papers have looked at this topic in some detail.

Bhalchandra *et al.* [8] looked at combined implanta-

tion of PP and AUS in 65 patients, 40 of whom had the implants performed simultaneously. The remaining patients had their PP inserted either before or after the AUS. In this study, a dual-incision approach was used as described above and the patients were grouped according to which AUS device was used, where group 1 were inserted with older AUS devices and group 2 were inserted with the AMS 800 sphincter. Over a mean of 35 months of follow-up, 90% of patients required one pad or less for continence and 98% of the PP were functional. 34% of patients in group 1 and 40% of patients in group 2 required revisions. Although this study did not distinguish those patients who had synchronous insertion of AUS and PP, two patients had the AUS components removed for infection, two had the PP removed for infection and further three had both sets of components removed for erosion of the cuff or cylinders, giving an overall erosion/infection rate of 11%. None of the inflatable PP required revision [8].

Kendirci *et al*. [10] looked at synchronous insertion of an AUS and inflatable PP via a single upper transverse scrotal incision in 22 men. In their series, at 17 months, 9% of patients had an erosion, with no infections noted [10]. No patient required more than one pad per day for continence.

There is little published data looking at the infection and erosion rate of combined implants. Two studies looking at this have reported an AUS infection/erosion rate of between 16% and 25% [10, 11]. In one study looking at 447 men with PP, the infection/erosion rate was 13% at 50 months follow-up [12].

The incidence of mechanical failure with the AUS device is 32% over the long term [11] but has been reported to be as low as 7.6% in one series which looked at the device after the introduction of the narrow-backed cuff [5]. In Minervini's series, the mechanical failure rate was 21% [13]. Bhalchandra's series showed a mechanical and technical failure rate of 48% overall with a proportionally higher rate of failure in the group where the older AUS device was used (62% *vs*. 25%) [8]. Kendirci's series reported reservoir migration in two (9%) patients [10].

Further reports on simultaneous insertion of AUS and PP are limited. In one study looking at the management of UI following prostatectomies of various sorts, four out of 37 patients had a synchronous insertion of an AUS and PP with no complications after a mean of 37 months follow-up [14]. Wilson reported on using an upper transverse scrotal incision to insert an AUS, with 11 out of the 37 patients also having an inflatable PP inserted through the same incision [6]. Most of these were placed in patients requiring revision AUS surgery. The incidence of infection was 9% and no patient had mechanical failure or atrophy at one year.

6 Outcomes of combination surgery

Combination therapy with the AUS and PP has been shown to be feasible, safe and an efficacious method for the surgical treatment of ED and UI. The patient satisfaction for either implant alone or in combination has been consistently and reproducibly high. The benefits are also obvious if one looks at cost and time savings with synchronous insertion. One study looking at this demonstrated reduced operation time using the synchronous approach as well as a cost savings of USD 7 000, compared with staged procedures [15].

Literature on irradiation and results of combination therapy with AUS and PP is scarce. In one series, the only erosions following synchronous insertion of an AUS and PP occurred in the irradiated patients post radical prostatectomy [10]. Previous irradiation in patients receiving an AUS has demonstrated higher revision rates in some studies [16] mostly due to urethral atrophy. Evidence on the risk of erosion and infection in the irradiated population with an AUS is inconsistent [16–19]. This issue is also confounded by the fact that erosion in the irradiated population may be due to the poorer quality of the irradiated tissue or to improper sizing of the urethral cuff or even by an unrecognized injury to the urethra during dissection.

Evidence on the use of PP in the context of the irradiated patient is relatively lacking. One paper studied the insertion of PP following radiotherapy for prostate cancer in 43 men [20]. At a mean follow-up of 40 months, 70% of patients were using their implant for sex. There were no incidences of infection or erosion, with only a 7% malfunction rate and a high satisfaction rate.

The results of the male perineal sling vary in the literature, however, intermediate follow-up demonstrates that 80%–93% are dry or socially dry (one pad or less per day) at 3–4 years follow-up [21, 22]. The male sling may be more suited to patients with no more than moderate UI and there is concern over the durability of this technique. Stringent patient selection will therefore continue to be important as this procedure is developed and its outcomes are assessed. In the only study looking at dual implantation of the sling and the PP [23] no patients were reported to have any peri-operative complications and the implication from this study is that at 1 year, no patients reported further complications and all four were dry and satisfied with the operation. It is still prudent, however, to apply the same patient selection criteria to this group as to those who are considered for the male sling only; that is, those with mild to moderate UI and who are also good candidates for a PP.

7 Technical considerations of simultaneous insertion of AUS and PP

Although simultaneous insertion of an AUS and PP is

appealing there are some drawbacks. Most authors report that it is easier to do the AUS portion of the insertion first, then start placing the penile components [8, 10]. Once the AUS cuff is in place, great care needs to be taken to avoid damaging the cuff and urethra while placing the PP cylinders. The respective tubing needs to be positioned such that tubing from one prosthesis does not interfere with that of the other.

In the event of an infection, the concern is that it will spread to all components necessitating their removal and making revision more challenging. Bhalchandra argues that in this situation, if one acts early to locate the components effected, it is possible to salvage the components of the unaffected device [8]. Erosion without infection may make salvaging one of the devices possible however in the context of infection, it can sometimes be very difficult to determine which components are affected. One would expect similar considerations in patients who have had a PP inserted in conjunction with a male sling, however, there is currently no published data looking at this.

8 Conclusion

Both the AUS and the PP are established treatments for urethral sphincter dysfunction and ED, respectively. With the high prevalence of both conditions and the increasing awareness of the treatments for these conditions, it is anticipated that more men will present to their physicians for a resolution to these debilitating problems. Additionally, concurrent ED and incontinence are increasingly seen in the post radical prostatectomy population, who are often younger and less willing to suffer with these conditions. Insertion of an AUS and PP, either simultaneously or as a two-stage procedure is a safe, efficacious and long-lasting solution to these problems. The technical design improvements of both the AUS and PP as well as the availability of the single transverse scrotal incision have made simultaneous insertion of these prostheses possible, with shorter net operating times, hospital stay and recovery time. Insertion of the PP in conjunction with the male perineal sling is still a relatively new approach to combination therapy and may find success in selected patients with mild to moderate stress UI who are also good candidates for PP. Patient satisfaction is consistently high and will continue to drive this combined approach.

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