



Twenty years later: is the scrotal one-incision AUS of value?

Steven K. Wilson¹ · O. Lenaine Westney² · John J. Mulcahy³

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Abstract

The artificial urinary sphincter, known as AMS 800, has been the gold standard for treating moderate to severe stress urinary incontinence in males for 40 years. Yet, the number of sphincters done globally is quite small and the majority of urologists doing them are infrequent implanters. Estimates for 2019 showed half of implanters did only one implant that year and worldwide only around 13,000 implantations were performed. The traditional two-incision technique of perineal exposure for cuff placement and abdominal incision for pump and pressure regulating balloon persists as the most common technique to surgically place an artificial urinary sphincter. Present estimates are that upwards of 80% are done via the perineal approach and that approach is the highly favored incision of large volume centers. The scrotal one-incision approach was invented by Wilson 20 years ago and was aimed at making the implantation of a sphincter quicker, easier and safer for the occasional implanter. These physicians perform 1–2 devices per year, comprise 60% of implanters who perform the surgery yearly, and implant 22% of all implanted devices. Our article targets these infrequent inserters discussing the history of the two techniques and what the authors have learned about the advantages and hazards of the one scrotal incision procedure over the last two decades.

Introduction

The artificial urinary sphincter (AUS) also now known as the AMS 800 (Boston Scientific) has been implanted for almost 4 decades in male patients suffering from stress urinary incontinence (SUI). The original 1973 publication was in the very first issue of the gold journal, *Urology*, then known as the orange journal [1]. The initial description of the implantation surgery utilized two incisions. Thirty years later a novel one-incision surgical technique for the device was described by Wilson utilizing a transverse scrotal incision [2].

When review articles are consulted for the outcomes of sphincter implantation, we find the majority of patients will achieve “social continence” which is defined as one pad

per day after AUS implantation. Rates of total continence (no pad usage) are significantly lower. Nevertheless, patient satisfaction with outcomes average greater than 80% in most series [3].

Compared with the inflatable penile prosthesis (IPP), the other urologic prosthetic invented by Dr. Scott, the 5-year device survival from revision is much worse. Sixty percent of first-time IPP will survive 15 years or more [4]. Recently, a multi-institutional study for AUS co-authored by Westney showed 5-year revision free survival to be 83% in first time patients but risk factors such as radiation and/or previous urethroplasty meant less than half the patients were able to achieve 5 years without a reoperation [5]. An older review article (2013) indicated the 5-year Kaplan–Meier freedom from revision reoperation ranged from 1/5th to over half of the cohort [6]. When compared with the revision frequency of other medical devices implanted in humans such as hips, knees, heart valves, breasts, and IPP, the AUS has some of the worst longevity [4]. Device infection rates are also higher than IPP despite antibiotic coatings on both devices. A recent article reported 3.2% in uncomplicated patients and 16.3% in radiated men [5]. A metaanalysis published in 2013 indicated an 8.5% overall infection rate on first time implants [7].

Irrespective of the previous paragraph, the AUS, as represented by the AMS 800, has been the gold standard for

✉ Steven K. Wilson
skwilson@mac.com

¹ Department of Urology, Institute for Urologic Excellence, La Quinta, CA, USA

² Department of Urology, University of Texas-M. D. Anderson Cancer Center, Houston, TX, USA

³ Department of Urology, University of Alabama, Birmingham, AL, USA

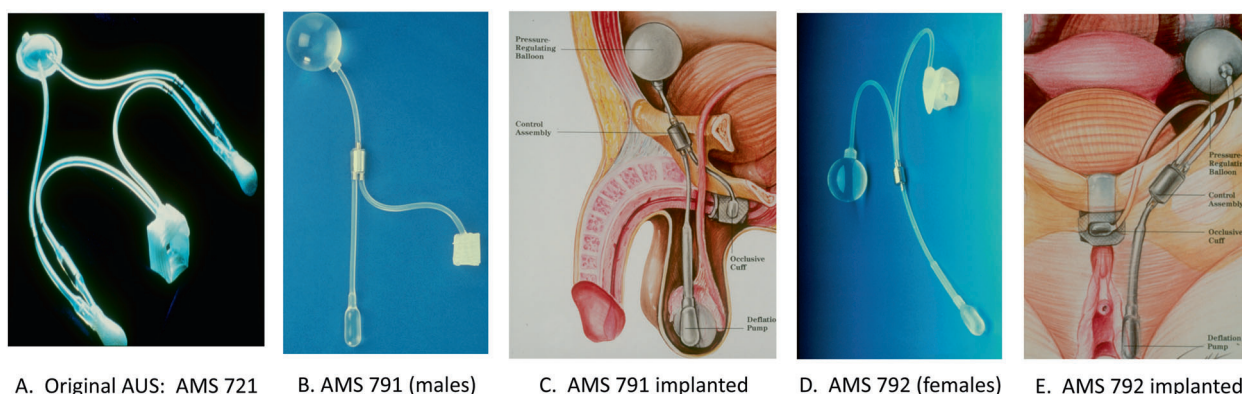


Fig. 1 Early artificial urinary sphincters.

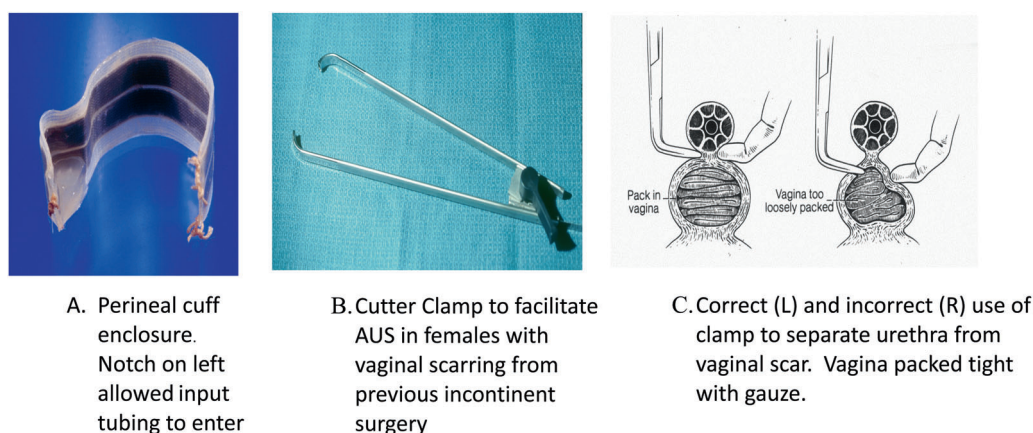


Fig. 2 Scott's AUS accessory enhancements.

treatment of moderate to severe SUI in males [7–9] for more than 40 years. This is simply because there is no better treatment available for the devastating quality of life issue that can be defined as the loss of urine without the owners' permission.

Physician demographics of the AUS

The statistical data of urologists performing the surgery is interesting. For such a prevalent affliction as male urinary incontinence following surgery, the numbers of AMS 800's done worldwide is shockingly small, in 2019 only 6000 in US and another 7000 outside the US (OUS). Currently there are just 11 surgeons globally (including our second author) who perform over 50 sphincters yearly. Five are in the US and six in Europe [10]. These centers do about 6% of the yearly AMS 800's. Of the other surgeons performing AUS, case volumes in and OUS were similarly low: 56% of implanters in the US and 52% outside the United States (OUS) perform only one surgical insertion yearly [11]. Boston Scientific estimates

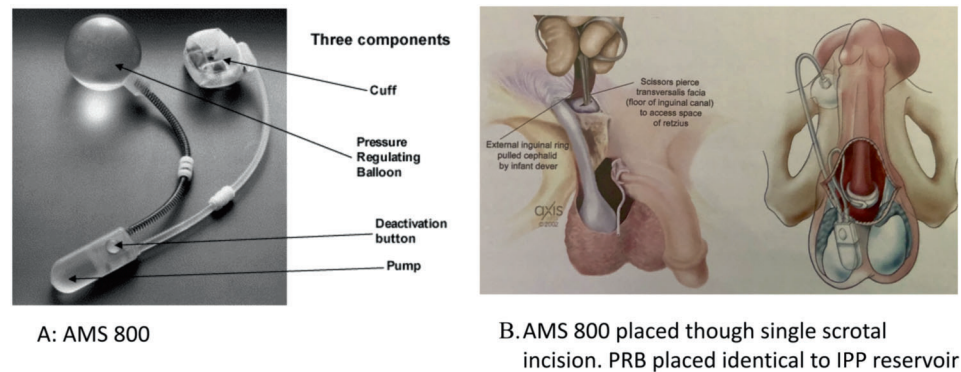
about 60% of surgeons did two or fewer cases for a total of 22% of all implanted devices. Approximately 40% of surgeons did three or more cases for a total of 78% of all implanted devices [10].

History of the AUS

Scott, a Professor of Urology at Baylor University in Houston TX, invented the device and first published it in 1973 [1]. Multiple milestones of device enhancement occurred over the next 9 years until he arrived at the AMS 800 we know today.

1. The original AUS was termed AMS 721 had two pumps, one for each hemiscrotum or labium majus (Fig. 1a). One pump filled the cuff the other emptied it. The patient kept pumping until he/she was dry. Cuff erosion was almost universal, and it was removed from the market in 1976.
2. The AMS 791 (males) (Fig. 1b, c) and AMS 792 (females) (Fig. 1d, e) appeared in 1979 with the first

Fig. 3 Today's AMS 800.



pressure regulating balloon (PRB) which slowly filled the cuff spontaneously after emptying it to void. Patients began using the device immediately after surgery and within 30 days 1/3 had cuff erosion. Furlow introduced the concept of primary deactivation to rest the urethra for 6–8 weeks and allow the capsule development to begin [12]. Unfortunately, these patients required an additional trip to surgery for activation.

3. Since many of Scott's patients rode horses and leaked with an AUS in place, he developed perineal cuff enclosure (Fig. 2a).
4. Placement of an AUS in a female with multiple previous anti-incontinence surgeries was a challenge due to excessive scar tissue between the urethra and vagina. Scott devised the "Cutter Clamp" to facilitate creation of a space for cuff placement around the bladder neck in such patients (Fig. 2b, c) [13].
5. In 1982 the AMS 800 was introduced with cuff, PRB and pump with deactivation button (Fig. 3a). The enhanced cuff had a tab and button closure, so it did not have to be fixed with four ties. The device is essentially the same today almost 40 years later except for the addition of a 4.0 and 3.5 cm cuffs and the application of infection retardant coating to the cuff and pump.
6. In the mid 1980's it became apparent the deactivation button was difficult for both patients and their physicians to operate. An AMS 830 was tested which had no abdominal components and was controlled by a magnet applied to the scrotal skin (Fig. 4). The company abandoned the project before it was marketed.
7. In 2010, Wilson and other implanters helped engineers design a pump that was like a light switch thinking that if the device could easily be turned off at night when most men with SUI are dry, cuff atrophy might occur less frequently. The enhanced pump was perfected but upper management chose to cancel the clinical trial. The explanation was funds were diverted

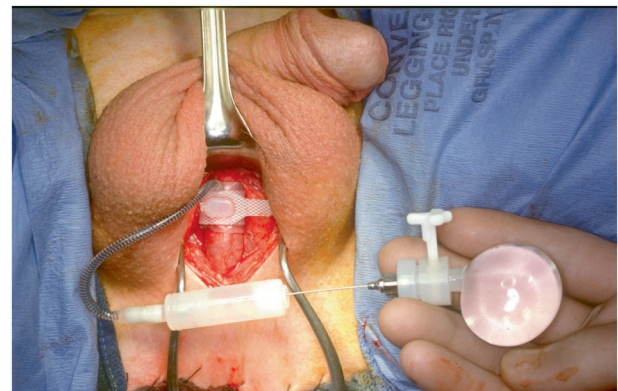


Fig. 4 AMS 830 Prototype.

to development of an external activation device for the IPP.

Scott and the early AUS implanters placed the device through two incisions. The patient was placed in high lithotomy with a perineal incision made for dissection of the urethra and placement of a silicone cuff circumferentially around the urethra. Next, an incision was made in the right lower quadrant of the abdomen and the PRB placed in the space of Retzius. The tubing from the cuff was tunneled up into the abdominal incision. After closing the transversalis fascia, the connections were made in the abdominal incision and the pump subsequently tunneled retrograde into a subdartos pouch created in the upper scrotum. The surgical insertion procedure remains relatively unchanged today. Over the years experienced surgeons have described enhancements of the original AUS placement technique in the following manner:

- Dr. Schreiter of Hamburg Germany promoted PRB location to be intraperitoneal in the 1980's. The practice persists at his institution today [14] but is not widely applied due to the potential risk of bowel obstruction.
- Mulcahy proposed inserting the pump via the original perineal incision to effect more dependent pump placement in 1999 (Fig. 5a–c) [15].

Fig. 5 Mulcahy's 2-incision pump fixation technique.

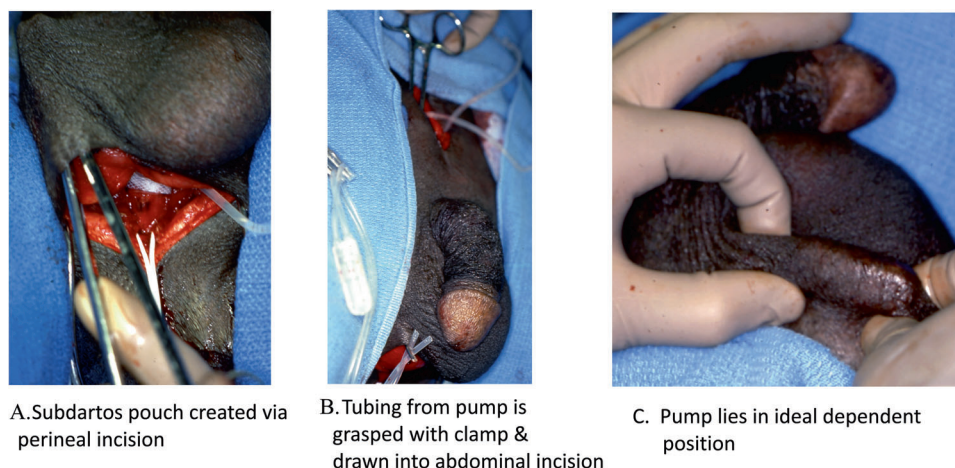
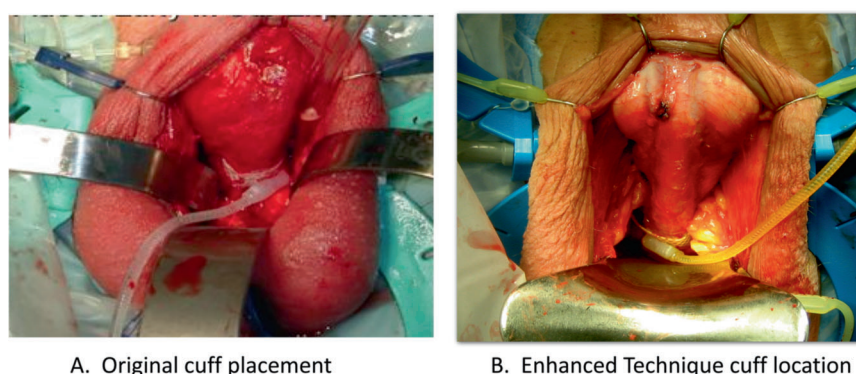


Fig. 6 Cuff locations on original and enhanced one-incision technique.



- Wilson and Delk suggested ectopic (also known as high submuscular or abdominal wall placement) of the PRB anterior to transversalis fascia and posterior to the muscle layers of the abdomen in 2003 [16]. Morey et al. published the first large series of successful high submuscular placement of balloons via a second high scrotal rather than abdominal incision [17].
- In 1993, Mulcahy advised placement of double cuffs (or tandem cuffs) in patients with severe incontinence or those who responded poorly to properly placed single cuffs [18]. This was quite popular initially but was relegated to only an occasional surgery after a long-term study showed an increased rate of urethral erosion [19].
- Dr. Webster recommended transcorporal placement of cuffs in patients who had required multiple revisions leaving them with only narrow distal urethral segments without scarring [20].

Steven Wilson a private practice physician in the sparsely populated state of Arkansas had attended Dr. Scott's second prosthetic workshop in 1974. He eventually performed the first IPP and AUS in his state and grew the practice by the 1990's to one of the largest prosthetic practices in the world. While his IPP volume was 300 per year, the number of sphincters yearly rarely broke 10. In

Wilson's opinion the perineal anatomy was a location rarely visited by the general urologist and the circumferential incision around the urethra for cuff placement was dangerous because the urethra was on stretch due to the high lithotomy patient position. In addition, two incisions were time consuming. He embarked upon a project to implant an AMS 800 through a variation of the same transverse scrotal incision used to implant IPP placing the PRB in the same way the reservoir is placed on an IPP (Fig. 3b) [2]. He specifically desired to avoid a separate incision for PRB and achieve better, more dependent positioning of the pump. He published his initial experience of 37 patients including 12 patients receiving a concomitant AUS and an IPP via the same one-incision technique. Wilson dubbed this procedure the AMS 1500 (AMS 700 IPP + AMS 800 AUS = AMS 1500)

After publication of this novel surgical technique, two camps quickly emerged. On the one hand, criticism and disbelief from the high-volume centers was rampant. Others wrote that the scrotal one-incision had similar outcomes to the traditional two incision [21]. Henry et al. spent 3 years as an associate of Wilson helping formulate the scrotal one-incision technique. Upon leaving the center, he published a retrospective review of the practice's sphincter experience contrasting the traditional approach to the new single

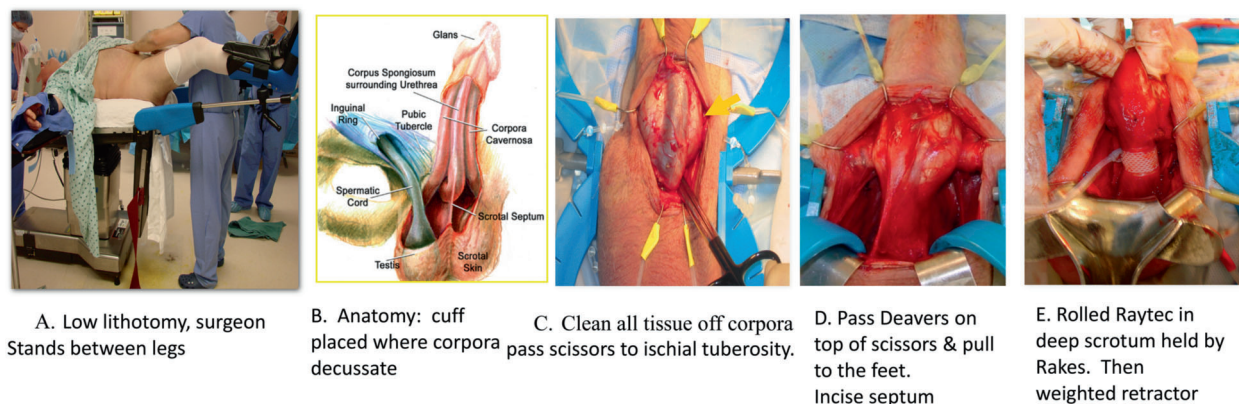
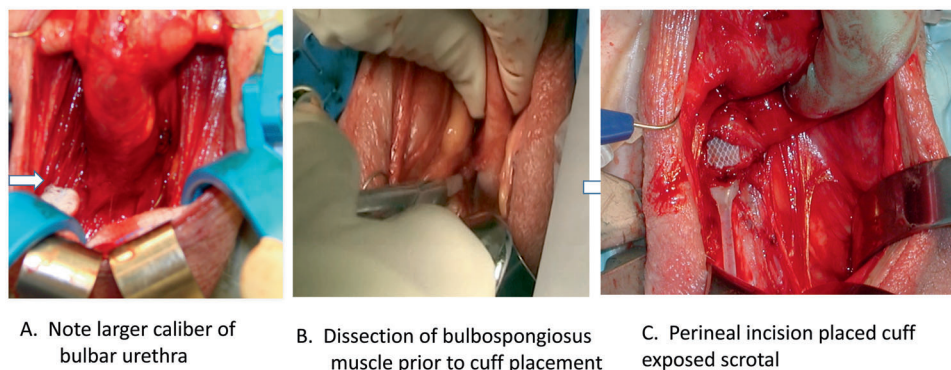


Fig. 7 Enhancements to the one scrotal incision technique.

Fig. 8 Mid bulbar urethra exposed via scrotal incision.



incision in development [22]. The study found a higher completely dry rate with the two-incision method of implantation. Henry followed that up with a multicenter study still using the original developing technique patients' results but adding several other centers and confirmed his original findings of less complete dryness but importantly noting that smaller cuffs were utilized in the one-incision group. This suggested the penoscrotal technique was placing the cuff on the more distal urethra which is smaller in diameter than the true bulbar urethra (Fig. 6) [23].

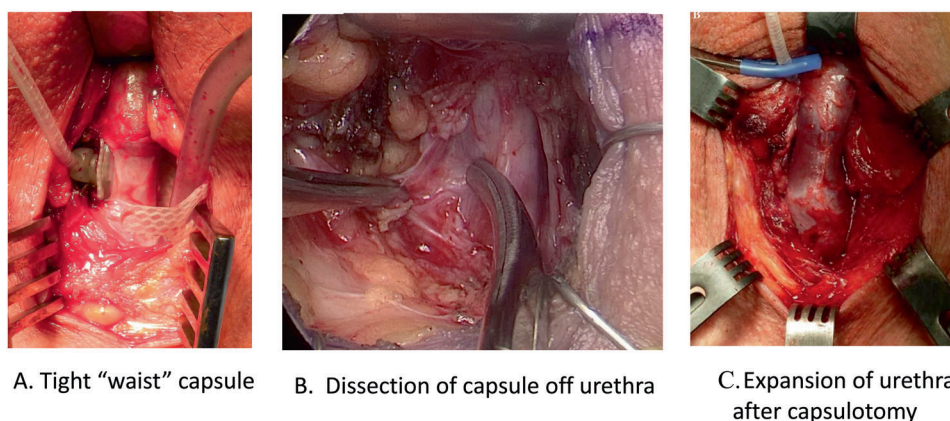
Wilson and Mulcahy went to work on meeting this valid criticism and improving the one-incision technique to expose the more proximal urethra. They changed the patient position from supine frog leg with surgeon at the side to low lithotomy with the surgeon between the legs (Fig. 7a). Employing the disposable SKW retractor rakes and rolled Raytec® sponges in the deep scrotum, they modified the exposure making the proximal urethra more visible (Fig. 7a–d). Finally, a medium Richardson retractor or weighted vaginal speculum (Fig. 7e) was employed to make certain the portion of the urethra that was a candidate for cuff placement was initially covered by the bulbospongiosus muscle (Fig. 8b) [24]. Twenty-seven patients were reported with ten revisions and five devices had been placed by the traditional two-incision technique. The new

technique enhancements allowed the majority of the patients to receive 4.5 cm cuffs rather than 4.0 cuffs that were the usual in the original patients' study. The team also noted that with the enhanced technique they were able to extract perineal incision placed cuffs through the scrotal incision (Fig. 8c) and achieve more proximal cuff replacement on scrotal incision placed cuffs performed with the original technique (Fig. 8c).

It is difficult to describe with prose a surgical procedure. The reader is directed to the Video Journal of Prosthetic Urology (VJPU) on the internet www.vjpu-issm.info where the following videos are described:

- Van Renterghem K. Perineal approach for artificial urinary sphincter implantation. VJPU. 2018;2:126
- Wilson S. Surgical tips for placing an AMS 800 through a single scrotal incision. VJPU. 2016;2:092 (enhanced technique)
- Van Renterghem K. Penoscrotal incision for primary implant AMS 800 artificial urinary sphincter. 2016;2:069 (some technique enhancements but not all utilized)
- Yafi FA, Richman A, Peak T, Mitchell G, Hellstrom WJG. Dual AUS/IPP Insertion through a single

Fig. 9 Cuff atrophy may really be capsular constriction.



penoscrotal incision. *VJPU*. 2015;2:049 (original technique)

The initial report of a male urethral sling not requiring a hydraulic device insertion in 2007 stimulated the interest of urologists and their incontinent patients alike [23]. It was an exciting development in male incontinence therapy that had scarce enhancement in the past decades. The AUS specifically had changed very little over the years. Male sling instructional courses were very popular, and the manufacturer recorded double digit sales growth every year until in 2010 twice as many slings were done globally as sphincters [10]. What is interesting is that sphincter’s yearly volume was never impacted by the new therapy for male incontinence—it remained constant. The availability of another remedy seemed to bring non AUS implanting urologists and their incontinent patients “out of the woodwork” to try the new male sling. Another factor may have been that patients who were using one or two pads per day were good candidates for a male sling and might have been hesitant to undergo AUS placement.

The status of the scrotal one-incision technique in 2020

Today the initial enthusiasm for the male sling has decreased significantly. Other invasive therapies have similarly come and gone. The AUS persists as the “gold standard” but overall usage remains small. The debate continues to rage concerning the two incisions. A large central European multicenter study of 473 implants comparing the two incisions showed that the penoscrotal approach was associated with an increased erosion rate [25]. A large middle European multi-institutional case series on the same subject by virtually all the same physicians reported on 467 patients [26] with scrotal single cuff implantation leading to significantly increased short-term explantation rates. This seems to be the same series of

patients and same reporting physicians described in two different journals but with a different publication title. The reader is asked to note the use of “central” in one paper and the use of the word “middle” in the other!

On the other side, a single surgeon series from Taiwan comparing the two incisions with a dozen patients in each cohort stated, “the penoscrotal approach for AUS implantation is easier and faster than the perineal approach with similar success rates in both approaches” [27]. Yafi et al. published a study of 77,512 AMS 800 patient information forms dating back to 1972. Surgeons doing two or less AUS yearly performed 83% of the cases and the perineal incision was used in 68% of the patients. He found younger age, penoscrotal incision, and dual cuff may be associated with inferior outcomes [28]. In 2020, Staniorski et al. reported Northwestern University data of 225 AUS of which 60% were placed scrotal and 40% perineal. Scrotal sphincter was significantly quicker and had significantly fewer revisions. Continence rates were similar [29]. Finally, at a 2019 Sexual Medicine meeting Jamaer et al. presented a 40 patient single surgeon series performed over the last 4 years using some but not all of the one scrotal incision technique enhancements. Noteworthy, the average cuff size was 4 cm. There were no infections, 80% were completely or socially dry and 10% required a revision. He concluded the penoscrotal advantages were “faster operating time (35 min), easier to execute, and exposure of anatomy is superior” [30].

Twenty years later: is the scrotal one-incision still valid?

Virtually all 11 implanters who perform >50 AUS yearly are fellowship trained reconstruction surgeons. These surgeons are comfortable in the perineum and utilize the traditional two-incision approach almost exclusively for first time implantations. The sphincter has a revision rate at or close to 50% in the first 5 years and this high revision rate is

similar each subsequent 5-year period [3]. For one who frequently experiences the perineal anatomy, the two-incision method in the lithotomy position does allow deeper urethral location of cuffs during either first time or revision surgery. The perineal or posterior scrotal incision for cuff placement is located directly over the site where the cuff is to be placed. If a more proximal or distal cuff location is needed, the incision may easily be extended or retracted in either direction to accommodate this. Certainly, removal and replacement of a cuff is more undemanding than through a scrotal incision. In addition, Mulcahy's placement of the pump via the perineal incision allows a dependent fixed location of this component avoiding the possibility of the so called "high riding" pump achieved with blind passage from above (Fig. 5).

Only very recently have authorities considered that what has been called cuff atrophy is actually capsular constriction. If the subcuff capsule around the urethra is incised, the urethral caliber will expand in real time, and a new cuff can be placed at the same site much larger than if the new cuff was placed on the spot without incising the capsule (Fig. 9). This cuff capsulotomy is now saving segments of new virgin urethra for future revisions [31, 32]. For the past 40 years, most episodes of cuff "atrophy" or erosion required a new virgin segment of urethra, either substitution of single cuff or addition of a double cuff. The tertiary referral centers would initially attempt revision via the traditional approach to explore a more proximal urethral segment but eventually employ the easier scrotal incision in the multiple revision patients because the only untouched candidate segment left on the urethra was the more distal scrotal urethra [32].

A minority of practicing urologists perform AUS. Those that do, perform the surgery once or twice a year. The articles listed above regarding the superiority of the traditional incision over the penoscrotal incision are flawed ... particularly the two Henry studies and the two large studies from "middle" or "central" Europe which seem to be the same study rephrased into another journal by the same authors [24, 33]. To the contrary, the small single surgeon series quoted above seem supportive of the one-incision technique. These surgeons find it easier, quicker and with similar outcomes to when the surgeons do the perineal approach [21, 27, 30]. The smallness of their series prevents our acceptance of these advantages as gospel. In summary, from our review of the literature, the jury is still out on a superiority of surgical technique. It seems valid from our standpoint to continue to provide an easier surgical technique for the large number of occasional physicians who might be tempted to perform an AUS while acknowledging that the tertiary centers will continue to place their cuffs more proximal on the urethra via the two-incision technique. We must always remember, however, that these centers only serve 6% of the patients receiving the device yearly

[10] and the remaining 94% of AUS are done by occasional prosthetic surgeons.

The direct access offered by the scrotal incision has acted as a "two edge sword". While urethral contact is more immediate with this approach, dissection must be extended proximally to the mid-proximal bulb to facilitate placement of the larger cuff. Progression to a more proximal dissection was a natural evolution for the experienced scrotal implanter with the benefit of case volume; however, the technical refinements described by Wilson and Mulcahy (Fig. 7) made attainment of the ideal exposure consistently obtainable by the occasional implanter. The use of the weighted retractor seems to neutralize anatomical patient differences in perineal length allowing each scrotal incision case to achieve proximal placement of the cuff with resultant use of a majority of 4.5 cm cuffs. One of the most natural applications for the scrotal approach is the patient in whom transcorporeal cuff placement is either planned or expected. Optimal access to the corpora and mid-distal bulbar urethra is obtained without the need for significant retraction as is necessary with the perineal incision.

It must also recognize that worldwide following their prostate surgery, there are a substantial number of untreated wet patients. Many of these men are angry and reluctant to seek a surgical solution because it was surgery that created this quality of life hindrance. After years of incontinence, if these men finally do consult a surgeon who does not do AUS, guess what happens? Rather than refer to a competitor, his physician may subterfuge and congratulate him on being a cancer survivor ignoring the fact that he is a survivor but a wet unhappy one. In another possible scenario, many cancer surgeons do not perform prosthetic placement. If the cancer surgeon refers his impotent and incontinent patients, he worries his reputation for potency preservation and urinary continence may be blemished. If the urologist consulted is an occasional AUS implanter, chances are he or she is not enthusiastic about recommending AUS because every device implantation is stressful for him/her. If a surgeon does a technique infrequently, he forgets the tricks of exposure increasing operative time and anguish. With any of these scenarios, the patient is not reassured to seek resolution of his problem and simply goes "back on the couch".

These patients need to be convinced by urologists that the AUS can improve their present existence. How do we get more urologists feeling positive about offering the AUS implantation without taking a reconstructive fellowship? Surgical confidence in the one-incision could be the answer. The three authors believe one scrotal incision method is quick, safe, easy to learn, and effective at diminishing incontinence particularly for a surgeon skilled at penoscrotal incision penile implant. We are reasonably certain the one scrotal incision technique performed by the

occasional implanter does not get the cuff as deep as a high-volume implanter employing the traditional incision (Fig. 6a). But we are also certain if the enhanced technique is followed, all surgeons can achieve cuff placement on that more robust portion of the urethra surrounded by the bulbospongiosus muscle which usually results in a 4.5 cm cuff (Figs. 6b, 7e.). In our opinion, that should equalize the true revision rates of the two incisions.

Compliance with ethical standards

Conflict of interest SKW: Consultant: AMT, Coloplast, International Medical Devices, Lecturer: Boston Scientific, Stockholder: NeoTract. OLW: Consultant: Boston Scientific. JJM: Consultant: Boston Scientific, Coloplast.

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