Penoscrotal Incision for the Primary Implantation of an Artificial Urinary Sphincter

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Abstract

Background: The artificial urinary sphincter (AUS) has become the gold standard to treat severe stress urinary incontinence in men. The traditional placement of an AUS requires 2 incisions. The cuff is placed through a perineal incision and the reservoir and pump are placed via an inguinal incision. The implantation of an AUS is also possible via a single penoscrotal approach. Objectives: The objective is to demonstrate that the penoscrotal approach is not inferior to the perineal approach. Methods: Retrospective review of a single surgeon database from 2014 to 2019 was performed. A total of 40 patients have undergone implantation of an AUS via a penoscrotal incision. The outcome of patients was followed for an average of 31.3 months for adverse outcomes. Results: A primary American Medical Systems 800 sphincter was placed in 40 patients via a penoscrotal incision. The average age was 72 years. The average operating time was 35 minutes. The average cuff size was 4 cm. There were no infections of the prothesis so far. Three patients required a revision, 2 other patients needed an explant of the AUS, 1 patient underwent a cystectomy because of persistent radiocystitis. After activation of the sphincter, 33 patients (82.5%) were completely dry or using 1 pad per day for accidents. The remainder were all improved. Conclusions: AUS implantation via a single penoscrotal approach is not inferior to the perineal approach and has several advantages. The operating time is shorter and the procedure requires only 1 incision which both reduce the risk of infections, while the continence results are similar for both approaches.

Introduction

Since the first description by Scott et al. [1] in 1974, the placement of an artificial urinary sphincter (AUS) is a frequently used method in the treatment of severe stress urinary incontinence in men when conservative and minimally invasive therapies have failed. This usually involves post-radical prostatectomy stress incontinence.

The AUS consists of 3 components: an inflatable cuff, a pressure regulating reservoir balloon, and a pump. The cuff is placed around the bulb urethra, the balloon retropubically intra- or extra-peritoneally, and the pump in a subdartos pouch. An incision is made in the fascia obliquus externus to create a channel for the kink-resistant connecting tubes. The system can be filled with physiological saline or contrast fluid. This sphincter is usually placed through 2 incisions: a perineal incision to place the cuff and an inguinal incision to place the balloon and the pump [2]. The most commonly used type of sphincter is the American Medical Systems (AMS) 800. In 2003, Wilson et al. [3] published a new method for placing the sphincter. In which the cuff, the balloon, and
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The dissection is carried deep enough on the posterior urethra to release the urethra. The use of the Scott retractor contributes to visualization of the urethra. Then a transverse penoscrotal incision technique is performed with the patient supine. A 16F lin are administered intravenously for prophylaxis. The scrotal povidone-iodine soap for 10 minutes and quinolone and penicillin are used to prevent infection. The dissection is carried deep enough on the posterior urethra until the bulbospongious muscle is visible for at least a centimeter. After dividing the bulbospongious muscle, the posterior urethra is dissected from the corpora cavernosa until there is sufficient space to place the cuff. Because the patient is not in the lithotomy position, the urethra is more mobile facilitating the posterior dissection [3]. The length of the cuff is measured circumferentially after removing the catheter.

The operation region is continuously rinsed with a dilute Amikacin solution. The balloon is placed in the cavity in the retropubic Retzius space created through the fascia obliquus externus, and filled with 25 ml isotonic fluid Omnipaque (300 mg). The fascia is then closed and the cuff is placed. A subdartos pouch is created and the sphincter pump is placed low mid-scrotally. Subsequently the different elements are connected and the operation field is flushed again with a dilute Amikacin solution. Subcutaneous sutures and skin staples are used to close the wound [4]. Finally, the sphincter is deactivated and a 12F transurethral catheter is placed. The catheter will be removed the day after the operation. The patient is discharged from the hospital if he had a good spontaneous miction. Seven days of postoperative antibiotics are prescribed. The patient is seen 1 week after the operation for wound checking and the sphincter is activated 6 weeks after the operation.

**Results**

Between 1 October 2014 and 1 May 2019, a primary AMS 800 sphincter was placed in 40 patients at the Jessa Hospital in Hasselt via a single penoscrotal incision. Incontinence etiology was due to radical prostatectomy in 27 patients. Nine subjects had radical prostatectomy plus radiotherapy. There were 4 patients developed severe stress incontinence after a transurethral resection of the prostate and 1 patient after an open prostatectomy for a benign disease. The final patient underwent resection of a chordoma at the level of the sacrum which caused stress urinary incontinence. The demographic data of the patient population are described in table 1.

On postoperative day 1, 3 patients developed urinary retention. These patients all responded to 24 hours of catheterization. Three patients (7.5%) required a revision: one for mechanical failure of the reservoir and 2 patients required downsizing of the cuff. An explant of the prosthesis was necessary in 2 other patients (5%): 1 patient developed erosion of the cuff 2 years after the operation and 1 patient developed progressive metastatic prostate cancer with local involvement. Finally, 2 patients required permanent deactivation of the sphincter: one because of increasing Alzheimer dementia and inability to use the sphincter safely and 1 patient because of persistent radiocystitis. There were no infections of the prosthesis (table 2). Preoperatively there was an average of 6 pads per day, with a range of 1–10 pads per day. After activation of the sphincter, 33 patients (82.5%) had at least a 50% reduction in pad use.

**Table 1. Demographic data of the patient population**

|                          | Values |
|--------------------------|--------|
| Total number of patients, n | 40     |
| Sex                      | male   |
| Average age, years       | 72 (46–86) |
| Average operating time, minutes | 35 (20–60) |
| Average cuff length, cm  | 4 (3.5–5) |
| Cuff length, n (%)       |        |
| 3.5 cm                   | 14 (35) |
| 4 cm                     | 18 (45) |
| 4.5 cm                   | 7 (17.5) |
| 5 cm                     | 1 (2.5)  |
| Social continent, n (%)  | 33 (82.5) |

At the start of the procedure, the genitalia are scrubbed with povidone-iodine soap for 10 minutes and quinolone and penicillin are administered intravenously for prophylaxis. The scrotal incision technique is performed with the patient supine. A 16F transurethral catheter is placed to empty the bladder in order to avoid injury during placement of the reservoir and to facilitate visualization of the urethra. Then a transverse penoscrotal incision is made followed by a dissection through the tunica dartos to release the urethra. The use of the Scott retractor contributes to a better exposition. The dissection is carried deep enough on the

**Materials and Methods**

In this study, 40 patients received a primary AMS 800 artificial sphincter via a single penoscrotal incision between 1 October 2014 and 1 May 2019 at the Jessa Hospital in Hasselt, Belgium. Demographic data were collected from their medical files (date of birth, etiology of incontinence, and previous treatments). In addition, the following operative data were collected: the date of the operation, the size of the cuff, and the operating time. The implantation was the first implant in all 40 patients. The recorded postoperative variables were functionality, continence, infection, erosion, atrophy, retention, and need for revision or explantation. The outcome of patients was followed for an average of 31.3 months with a range of 12.1–55.8 months, for adverse outcomes. According to the local ethical committee guidelines, medical information was retrospectively obtained within the treating physician-patient relationship.

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Discussion

Over 400 articles have been published on the use of an AUS in male patients with urinary incontinence. These articles are mainly retrospective, and a comparison of results is often made difficultly by the heterogeneity of the patient groups and the variety of definitions of continence used. Overall, the studies suggest that the AUS achieves good long-term results with an average percentage of socially continent patients of 79% (61–100%), with a follow-up period range of 5–192 months. The percentage of postoperative socially continent patients was similar (82.5%) in our study [5]. Nevertheless, 26% of the patients underwent a re-intervention and the frequency of revisions increased with the duration of follow-up [6]. In our study the revision percentage was 7.5%.

An infection of the AUS is a serious complication that usually occurs in the first 2 years after implantation [5]. If there is an infection, the AUS must be explanted as soon as possible [7]. The infection rate in recent studies varied from 1 to 8% [5]. No infections occurred in our study. In our view, the penoscrotal technique offers a number of advantages that can help reduce the risk of infection. The simpler technique leads to a significantly shorter operating time which is crucial in prosthetic surgery. The experience of the surgeon also plays a decisive role. Our study was performed by a single very experienced surgeon, whereas most of the articles are based on multiple surgeons who were not all used to operating penoscrotally.

Compression of the cuff on the urethra can lead to urethral atrophy via ischemic tissue, resulting in a reduction of the urethral diameter [6]. As a result, the cuff can become too large in relative terms and can lead to recurrent urinary incontinence after an initial continent period. On average, urethral atrophy occurs in 7.9% (1.9–28.6%) of patients. There are several therapeutic options if urethral atrophy occurs. A second cuff can be placed (“tandem cuff”) or alternatively a new cuff can be provided transcorporally. As a third option, the cuff can be placed more proximally where the caliber of the urethra is larger. Finally, the cuff length can also be reduced. A pressure increase of the cuff, however, is not recommended as it can lead to ischemia which can subsequently cause erosion of the urethra [6]. Several authors suggest that the cuff can be placed more distally with the penoscrotal procedure than with the perineal procedure. However, the experience of the surgeon and a good anatomic exposure during the operation are important variables that affect the placement of the cuff. The most commonly used AMS 800 cuff size is 4 cm according to Ratan et al. [2]. The average cuff size used in our study was also 4 cm. This most likely indicates an equally proximally placed cuff.

There are different techniques for placing the cuff: perineal, penoscrotal, preserving the bulbospongious muscle, and transcorporal. We detached the bulbospongious muscle as in the classical technique. The placement of AUS preserving the bulbospongious muscle has been reported to have excellent continence rates and lower urethral erosion rates [8]. Using a transcorporal procedure, the urethral cuff is placed through the corpora cavernosa to obtain additional tissue between the cuff and the urethral lumen, without further mobilization of the urethra. Placing the tunic a albuginea between the cuff and the urethral body provides additional bulking [9]. It might be a good salvage therapy for complex failure of male slings, but in our opinion, there can be a postoperative erectile dysfunction.

Pearlman et al. [10] questioned the occurrence of urethral atrophy and suggested an alternative explanation for late AUS dysfunction. They suggested that a fibrous cap forms around the components of the AUS after a few weeks. This cap can also form around the cuff and thus contribute to a caliber reduction of the urethra. When the fibrous cap is removed, the original urethral caliber recovers, explaining the absence of atrophy in their opinion. Bugeja et al. [11] therefore argued that recurrent in-
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continence is caused by long-term failure of the material and that a replacement of the AUS suffices to solve this problem.

Urethral erosion is another serious complication. Erosion that postoperatively occurs within the first months is considered of iatrogenic origin caused by urethral trauma during the placement of the AUS. If the erosion occurs later, it can be caused by urethral compression through the cuff. Therefore, long-term (> 48 hours) catheterizing of a patient with an AUS is an important risk factor that contributes to urethral erosion [12]. Cystoscopy is needed to distinguish erosion from atrophy. Atrophy does not cause an infection of the sphincter [11]. Urethral erosion always produces a secondary infection. This is important because of the difference in treatment of these problems. In case of erosion, the AUS needs to be explanted.

Mechanical failure of the AUS can also give rise to persistent or recurrent incontinence. Mechanical failure of the AUS can occur primarily or secondarily with a previously functional sphincter. There is no consensus about the optimal treatment for mechanical failure. One option is to replace only the defective part of the AUS [13]. In our study, there was 1 case of mechanical failure. The reservoir was refilled and the pump was replaced with good postoperative functionality.

Acute urinary retention following AUS occurs in most series of implantations, but this is often transient and may be due to postoperative urethral edema. The urine retention usually spontaneously disappears within a few days. In our study there were 3 patients with urinary retention which required 1 day of catheterization, and after this the problem was resolved.

We note that our study scores well in terms of complications and revision. However, our relatively limited follow-up period must be considered. After all, the revision rate increases with time. The average time to revision is 28.9 months according to several multi-institutional studies [14]. In our study the average time to revision was 17.1 months, with a range of 3.2–44 months, due to a shorter follow-up period.

Several authors, however, are critical of the penoscrotal technique. Henry et al. [15] stated that in their study, in which 201 sphincters were placed (90 penoscrotal and 111 perineal), the perineal technique was superior to the penoscrotal technique. They concluded that the penineal technique scores better in terms of continence: in the penoscrotal procedure 71.1% of the patients appeared to be continent compared to 77.4% in the perineal technique, but statistically this was not a significant difference. According to this multicentric study with a low volume of surgeons, this difference could be caused by the more proximal placement of the cuff in the perineal technique. They argued that a penoscrotal technique would lead to the use of smaller cuffs. However, we observed that our study scores were even better than the perineal series of Henry et al. [15] in terms of continence with respectively 82.5% of patients socially continent utilizing the penoscrotal technique in this study.

Kretschmer et al. [16] argued that the perineal technique is superior in terms of explant ratio in the short term (6 months) with an explant ratio of 8.6% compared to 19.2% in the penoscrotal technique. In our study 2 explantations (5%) were required, one because of erosion and the other because of the development of progressive metastatic prostate cancer with local involvement.

Yafi et al. [17] found in a recent retrospective analysis that the penoscrotal technique resulted in a significant higher number of erosions, a significantly higher number of infections, and significantly more explants and revisions. This concerns a multicentric, low volume study. We were not able to confirm these conclusions in our study (table 2).

Sotelo et al. [18] concluded in their retrospective multicenter study with 83 AUS placed with the penoscrotal technique, that the penoscrotal technique is not inferior to the perineal technique. A total of 83% of the patients in their study were socially continent with an average follow-up duration of 18.8 months. This study also scored better than average in postoperative complications such as erosion and infections, despite the fact that 24 patients underwent radiotherapy and 4 patients underwent cryo-therapy.

Kendirci et al. [19] stated in their multi-institutional, retrospective analysis of 22 patients that the penoscrotal technique is superior. In their series, 100% of the patients turned out to be socially continent and complications were minor with only 3 revisions (14%) (two of them due to erosion and one due to migration of the reservoir). Migration of the reservoir did not occur in our study.

Shen et al. [20] also concluded in their study of 27 AUS (12 perineal and 15 penoscrotal) that there is no significant difference between the techniques in terms of continence and complications. It was also established that the duration of the operation with the penoscrotal technique was shorter than with the perineal technique, with an operating time of 86.0 ± 21.1 minutes for the penoscrotal technique and 115.4 ± 32 minutes for the perineal technique. This is still significantly longer than the average duration of surgery in our study of 34.7 minutes (20–60 minutes) [21]. Both the study of Kendirci et al.
[19] and Shen et al. [20] were multicenter studies with a small patient population and so concerned low volume implanters. We want to highlight that this operation should be performed in an expert center with high volume implanters. Otherwise, a fair comparison cannot be made with the technique that has been in use for years and applied by the majority of urologists.

**Conclusion**

We conclude that the implantation of an AUS via a penoscrotal approach is not inferior to the perineal approach. In our opinion, the penoscrotal approach has many advantages: it offers easier and quicker exposure of the urethra; it only requires 1 incision, and a significantly shorter operation time. While we, unfortunately, did not track pain medication usage in our patients, we have the distinct impression that the postoperative course following scrotal incision is experienced as less painful than the perineal incision. These advantages ultimately result in a reduced infection risk without loss of quality and outcome.

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