A Multicenter Study on the Perineal Versus Penoscrotal Approach for Implantation of an Artificial Urinary Sphincter: Cuff Size and Control of Male Stress Urinary Incontinence

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Abbreviations and Acronyms

AUS = artificial urinary sphincter
IP = initial perineal
IS = initial scrotal
RP = revision perineal
RRP = radical retropubic prostatectomy
RS = revision scrotal
XRT = external beam radiation

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Purpose: In a single center retrospective study we previously reported superior dry rates and fewer artificial urinary sphincter revisions when the sphincter cuff was placed via the traditional perineal approach compared with a penoscrotal approach. A multicenter study was performed to compare the approaches further and explain the disparity in outcomes.

Materials and Methods: We performed a retrospective review of 158 patients who underwent these procedures from April 1987 to October 2007 at 4 centers.

Results: During 184 surgeries in 158 patients 201 artificial urinary sphincter cuffs were placed (90 penoscrotal and 111 perineal). Among patients with known followup the completely dry rate for single cuff artificial urinary sphincters was 17 of 62 (27.4%) in the penoscrotal group and 41 of 93 (44.1%) in the perineal group ($p = 0.04$). Continued incontinence necessitated subsequent tandem cuff in 7 of the 62 (11.3%) penoscrotal cases compared to only 5 of the 93 (5.4%) perineal cases. Cuff size in the penoscrotal group was 5.0 cm in 1 patient (1.1%), 4.5 cm in 11 (12.2%) and 4.0 cm in 78 (86.7%). Cuff size in the perineal group was 5.5 cm in 1 patient (0.9%), 5.0 cm in 8 (7.2%), 4.5 cm in 30 (27.0%) and 4.0 cm in 72 (64.9%).

Conclusions: There appears to be a higher completely dry rate with fewer subsequent tandem cuff additions with the perineal approach compared to the penoscrotal approach. This disparity may be explained by a more proximal artificial urinary sphincter cuff placement in the perineal group as evidenced by a larger cuff size.

Key Words: urinary incontinence; urinary sphincter, artificial; urethra; genitalia, male

SINCE the first published article by Scott et al in 1974 on AUS implantation for urinary incontinence, the traditional surgical procedure has involved a perineal incision for cuff placement and a lower abdominal incision for placement of the pressure regulating balloon and pump.[1–7] In 2003 Wilson et al presented a novel method of implantation via a single upper transverse scrotal incision.[8] All parts of the AUS can be placed via this incision and early results were encouraging. At a mean followup of 12 months 66% (25 of 37) of patients were completely dry and there was no difference in complication rates compared to the traditional method. Use of the transscrotal (penoscrotal)

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technique has been increasing for 5 years as proponents believe there is no difference in functional outcome or device survival. However, some experts believe there is a difference between the perineal and transscrotal approaches.[9]

Recently we published a single center longitudinal study of more than 15 years of experience in 94 patients comparing the 2 common approaches for cuff placement.[10] Although the transscrotal approach is faster and easier for most urologists to perform, we noted that even among surgeons experienced with the penoscrotal approach there appeared to be an advantage to the perineal approach. Completely dry rates were 28.6% in the penoscrotal group and 56.5% in the perineal ($p = 0.01$), while 17.9% of the penoscrotal group required subsequent tandem cuff compared with only 3.1% of those in the perineal group ($p = 0.06$). Advocates of the transscrotal approach claim they are placing the AUS cuff in the same location as with the perineal approach and achieving similar continence (unpublished data). Therefore, a multicenter study was performed to compare these 2 common surgical approaches further to explain the disparity in outcomes. Specifically we analyzed AUS cuff size to determine if the cuff location was different in the 2 techniques, as well as continence rates, subsequent tandem cuff additions and revision rates.

MATERIALS AND METHODS

We reviewed the charts of 158 consecutive patients who underwent AUS placement by 6 surgeons from April 1987 to October 2007 at 4 centers. To the best of our knowledge this review included all consecutively performed surgeries by the 6 surgeons. Each AUS cuff was placed on the bulbar/penile urethra. Surgeon preference was used for single vs double cuff initial placement and the approach chosen for each patient, with 5 of the surgeons using both approaches and only 1 performing only the perineal approach. Institutional review board approval was obtained for the study.

Standard preoperative evaluation included a history and physical examination, cystoscopy, urinalysis and selective use of urodynamics. The etiology of incontinence was RRP alone in 143 patients (71.1%), RRP plus XRT in 24 (11.9%), transurethral resection of the prostate alone in 10 (5%), XRT alone in 7 (3.5%), neurological cause in 6 (3%), salvage RRP after XRT in 4 (2%), radical cystoprostatectomy in 3 (1.5%), transurethral resection of the prostate plus XRT in 2 (1%) and laparoscopic prostatectomy in 2 (1%). Surgical techniques for the perineal and penoscrotal approaches have been previously described.[8,11]

Patient medical records and operative reports were reviewed for demographic and preoperative variables including age at implantation, race, etiology of incontinence, type of prior treatment for incontinence and daily preoperative pad use. Surgical variables recorded include the date of surgery, initial implant or revision, surgical approach (scrotal or perineal), AUS cuff size and presence of any synchronous surgical procedure including penile prosthesis implantation. Postoperative outcomes were recorded, and included continence rate, number of pads (if any) used daily, complications (infection/erosion, malfunction, atrophy), months to revision (if applicable), revision type and total months of followup.

Nonparametric mechanical failure-free duration curves were computed using the Kaplan-Meier product limit method.[12] The patients were separated into 2 groups and subgroups for analysis, with patients in group 1 undergoing primary implantation of an AUS, perineal vs transscrotal approach, and patients in group 2 undergoing revision/replacement of an AUS, perineal vs transscrotal approach. Subgroups were identified as initial perineal, initial scrotal, revision perineal and revision scrotal. Separate curves were estimated for each of the 4 patient subgroups and then the 2 subgroup curves in each group were compared using the log rank test.[12] Data management and analysis were performed using Stata® version 8.0.[13]

RESULTS

Patients

The medical records of 158 male patients at 4 centers were reviewed for this study. Inflatable penile prostheses were placed simultaneously for erectile dysfunction in 42 patients. A total of 17 patients underwent initial double cuff placement via the perineal approach in 6 and the scrotal approach in 11. Patients were classified into 4 subgroups of IS 49 (31.0%), IP 70 (44.3%), RS 20 (12.7%) and RP 19 (12.0%). Mean age at surgery in all groups was 68.6 years (range 30 to 94). There was no significant difference among the groups in terms of etiology, race or age except mean age between the RS (73.3 years) and RP groups (65.2) ($p = 0.002$). Mean preoperative daily pad use in 158 patients was 4.7 (range 1 to 12), which did not vary among the subgroups. Preoperative details for each group are listed in table 1.

Procedures

During 184 surgeries 201 AUS cuffs were placed (90 via the penoscrotal approach and 111 via the perineal approach). In patients with known followup the completely dry rate for single cuff AUS was 17 of 62

Table 1. *Preoperative variables*

	No. Pts	Mean Age at Surgery	Mean Pads/Day (range)	No. Procedures for Stress Urinary Incontinence Due to RRP (%)
RS	20	73.3	5.5 (1.5–10)*	30 (85.7)
RP	19	65.2	3.7 (2–10)	35 (97.2)
IS	49	69.4	5.4 (1–12)	38 (69.1)
IP	70	66.5	5.2 (2–10)*	40 (53.3)
Overall	158	68.6	4.7 (1–12)	143 (71.1)

* Two patients were not counted in this average, 1 using a condom catheter, and 1 using a clamp and pads.

Table 2. *Postoperative completely dry and social continence rates*

	No. Procedures With Adequate Followup	No. Completely Dry (%)	p Value	No. Socially Continent (%)	p Value
Single cuff procedures:					
RS	11	4 (36.4)	<0.19	6 (54.5)	<0.10
RP	18	11 (61.1)		15 (83.3)	
IS	38	13 (34.2)	<0.05	27 (71.1)	<0.50
IP	53	30 (56.6)		41 (77.4)	
Totals	120	58 (48.3)		89 (74.2)	
All procedures:					
RS	14	6 (42.9)	<0.40	8 (57.1)	<0.20
RP	24	14 (58.3)		19 (79.2)	
IS	46	20 (43.5)	<0.20	35 (76.1)	<0.90
IP	57	33 (57.9)		44 (77.2)	
Totals	141	73 (51.8)		106 (75.2)	

(27.4%) in the penoscrotal group and 41 of 93 (44.1%) in the perineal group (p = 0.04). Of the 184 cases 119 (64.7%) were initial surgeries and 65 (35.3%) were revisions, with 105 (57.1%) perineal and 79 (42.9%) scrotal approaches.

Outcomes and Followup

Dry rates for single cuff AUS were 27.4% (17 of 62 patients) in the penoscrotal group and 44.1% (41 of 93) in the perineal group (p = 0.04). Subsequent tandem cuff was necessary due to persistent incontinence in 7 of the 62 (11.3%) penoscrotal cases compared with only 5 of the 93 (5.4%) perineal cases. During 141 (76.6%) procedures with known continence followup 120 had a single cuff was placed in 120 and double cuffs or a tandem cuff was placed in 21.

For initial single cuff implantations 34.2% (13 of 38) of patients in the IS group and 56.6% (30 of 53) in the IP group were completely dry (no pad use at all) (p = 0.03). Completely dry rates for the RS and RP groups were 36.4% (4 of 11) and 61.1% (11 of 18), respectively (p = 0.19). Socially continent rates (defined as 1 pad or less daily) for all groups undergoing single cuff placement are shown in table 2. The overall completely dry rate for all procedures with known continence followup (141) in this study was 51.8% and the overall socially continent rate was 75.2%.

Postoperative complications included mechanical failure, cuff, erosion/infection and urethral atrophy (table 3). The most common complication overall was mechanical failure of the AUS resulting in recurrent incontinence in 17.9% (33 of 184) of all procedures. The total complication rate per subgroup was 53.3%, 54.3%, 22.0% and 27.5% for RS, RP, IS and IP, respectively. For the IS and IP groups tandem cuffs were later added in 10% and 1.4% of cases, respectively (p = 0.04, fig. 1). Estimated failure-free survival did not significantly differ during the time between the initial implant and the revision groups (fig. 2).

AUS Cuff Size

Cuff sizes were also compared. Of the 90 cuffs placed penoscrotally 1 (1.1%) measured 5.0 cm, 11 (12.2%) measured 4.5 cm and 78 (86.7%) were 4.0 cm. Of the 111 cuffs placed perineally 8 (7.2%) measured 5.0

Table 3. *Postoperative complications and management*

	RS	RP	IS	IP	Totals
No. postop complications (%):					
Malfunction	4 (25.0)	11 (57.9)	9 (81.8)	9 (47.4)	33 (17.9)
Erosion/infection	11 (68.8)	7 (36.8)	2 (18.2)	6 (31.6)	26 (14.1)
Urethral atrophy	1 (6.2)	1 (5.3)	0	4 (21.0)	6 (3.3)
Totals	16 (53.3)	19 (54.3)	11 (22.0)	19 (27.5)	65 (35.3)
No. revision type (%):					
Revision	8 (26.7)	8 (22.9)	2 (4.0)	8 (11.6)	26 (14.1)
Removal	6 (20.0)	9 (25.7)	2 (4.0)	13 (18.8)*	30 (16.3)
Tandem cuff added	2 (6.7)	4 (11.4)	5 (10.0)	1 (1.4)†	12 (6.5)
Totals	16 (50.0)	21 (60.0)	9 (18.0)	22 (30.4)	68 (37.0)

* p = 0.02.
† p = 0.04.

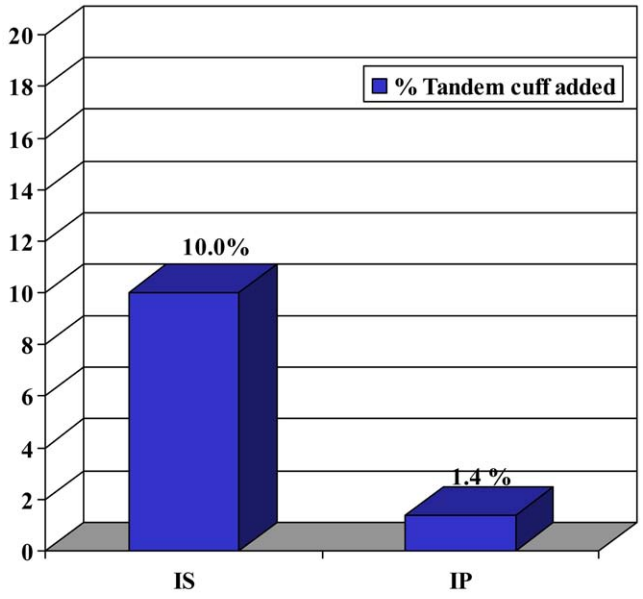

Figure 1. Number of patients who later underwent tandem cuff addition after initial scrotal approach vs initial perineal approach.

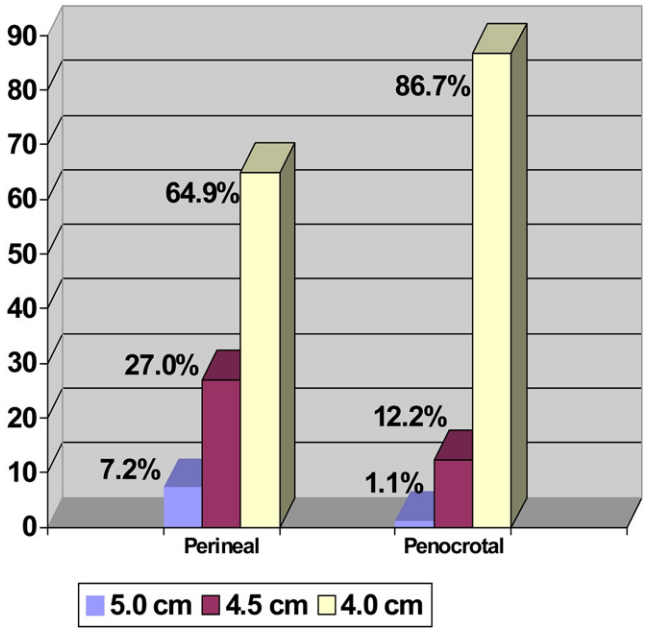

Figure 3. Cuff size use for perineal and penoscrotal approach to AUS cuff placement.

cm, 30 (27.0%) were 4.5 cm and 72 (64.9%) were 4.0 cm (fig. 3).

DISCUSSION

AUS bulbar cuff placement via a perineal incision had been the preferred approach until Wilson et al introduced the single incision transscrotal approach in 2003.[8] Increased use of the transscrotal incision has occurred despite any comparison study between the 2 approaches. In a recent single center retrospective review we reported superior dry rates and fewer surgical revisions with cuffs placed perineally vs transscrotally.[10] Our findings were challenged by those who favor the transscrotal approach because they have not experienced a meaningful difference in outcome.[9] Consequently we elected to perform a multicenter study comparing dry rates of perineal vs transscrotal cuff placement. The urethral caliber becomes progressively smaller from mid bulb to urethral meatus, thereby necessitating a smaller cuff size at a distal site. Therefore, we also compared cuff sizes used to determine if the cuffs were located in a comparable location.

The term social continence has ranged in use from 0 to 2 pads daily, although it is more commonly understood (and defined in this study) as 1 pad or fewer daily.[14,15] The overall completely dry rate for all patients with known followup in the current study was 51.8% and 75.2% were socially continent. Similar results for dry and

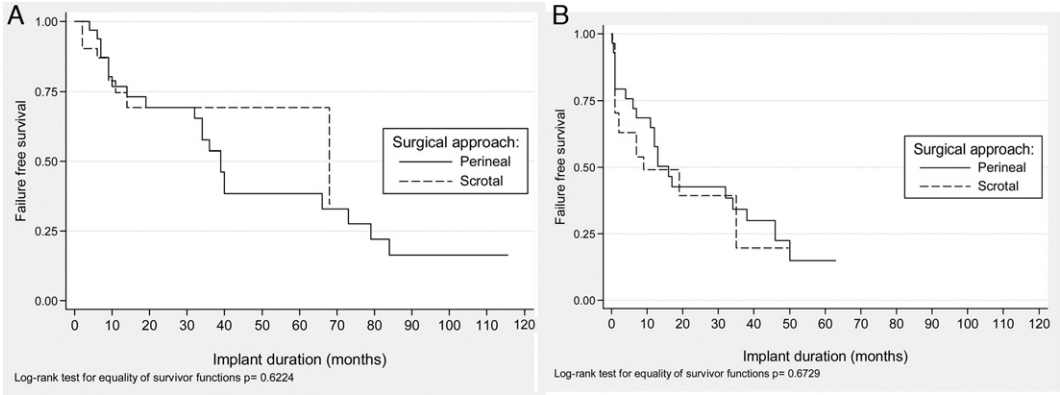

Figure 2. Kaplan-Meier product limit estimated failure-free survival of initial implants (*A*) and revised implants (*B*) stratified by surgical approach.

social continence rates were reported for 218 patients by Lai et al at 35% and 69%, respectively,[16] for 71 patients by Gousse et al at 27% and 59%, respectively,[17] and for 113 patients by Montague et al at 64% (social continent rate only).[5] Based on 120 procedures with single cuffs placed and known followup we found that 17 (34.7%) of the 49 patients who underwent scrotal placement and 41 (57.7%) of the 71 who underwent perineal placement were completely dry ($p = 0.01$). Further stratifying the scrotal and perineal procedures into revision and initial implants we found that all comparisons of completely dry rates for patients with single cuffs favored the perineal approach (table 2). Moreover patients in the IP group were older at placement and had longer followup with better outcomes than those in the IS group, an even stronger argument that the perineal approach should be the incision of choice for surgeons who can perform both approaches with equal skill.

Postoperative complications including malfunction, erosion and urethral atrophy were similar among groups. Our results regarding complication rates are similar to those of Venn et al, who reported a 66% revision/removal rate for male bulbar urethral cuffs.[4] The various types of followup procedures were recorded separately as device removals, revisions and tandem cuff additions. Kaplan-Meier curves comparing perineal vs transscrotal approaches for initial implants and revisions did not show any significant differences in product durability.

Since the penoscrotal approach limits the number of incisions and expedites genitourinary prosthesis placement, it has rapidly evolved into a primary procedure for post-prostatectomy incontinence. The proponents of the transscrotal approach also argue that this technique allows a more straightforward urethral mobilization due to improved exposure and laxity of the bulbar urethra.[8] They also believe placing the cuff around the urethra as it emerges from the diverging corpora is the same location as that achieved by the traditional perineal approach.[8] Skeptics of the transscrotal technique argue that the cuff is not placed around the proximal bulbar urethra as in the perineal approach, but is rather positioned around the distal bulbar urethra.[18] This argument originates from the initial description of the technique, which states that the "bulbospongious muscle is never divided, rather it is simply displaced," implying that that the cuff location is the distal bulbar urethra.[8,18] Recognizing that as the urethral caliber becomes progressively smaller distally, a smaller cuff size indicates a more distal location.

A distally placed cuff on a thin urethra may lead to more revisions due to a loose fit and accelerated urethral atrophy compared with perineal cuff placement at a more robust proximal bulb of the urethra.

There is a significant difference in cuff size in the penoscrotal series by Wilson et al compared with historical data from the Mayo Clinic.[8] In the study by Wilson et al 32 of 37 (86%) cuffs were 4.0 cm. Conversely in a study from the Mayo Clinic Elliott and Barrett noted that 267 of 272 (98%) perineal cuffs were 4.5 cm, 5 of the 267 (2%) were 5.0 cm and none of the cuffs placed primarily were 4.0 cm.[19] The disparity in cuff size in the Mayo Clinic (perineal incision) vs the Wilson et al (penoscrotal incision) data makes a compelling argument that the cuffs placed via a transscrotal incision are in fact at the distal bulbar urethra. However, recognizing that no standards exist in selecting cuff size, this can be a subjective process resulting in differences in cuff size between 2 series. Moreover the 2 series are from different periods and at different centers, which also may have resulted in a disparity in cuff size.

Therefore, we examined cuff size in our patients implanted using the 2 approaches for bulbar cuff placement. In our multicenter review we noted a significant difference in cuff size, that is, 4.0 cm cuffs were placed in 86.7% with the penoscrotal approach vs 64.9% with the perineal approach.

Despite all the surgical advantages of the transscrotal technique, according to our multicenter review the perineal approach is superior with respect to completely dry rates and social continence rates. This observation is further supported by similar complication rates and the longevity of the device with either approach. In addition, the perineal approach is supported by numerous studies from multiple centers with good results and long-term followup.[2–5,15,17] However, the transscrotal approach is only 5 years old and there are only limited data supporting its use.[8] There will be a 3.5 cm cuff available soon for AUS that may benefit the outcome of incontinence rates with the penoscrotal approach.

There were several limitations in the design and outcome analysis of this study that could be improved by future studies. The study was retrospective, and would benefit from a prospective, randomized trial evaluating the same outcomes and using patient satisfaction questionnaires. Variables like operative times and perioperative blood loss were not recorded, and some hospital charts after 15 years were no longer available to obtain that information. This also affected how we measured AUS success (with patient pad use). In a recent study the 24-hour pad weight test was shown to correlate more closely with urinary leak than patient reported pad use.[20] Despite this relatively new standard of pad weight Gousse et al found that the degree of patient satisfaction in their study correlated with the number of pads used ($p < 0.0005$).[17] Nevertheless, many of the procedures in this study were performed more than 5 years ago before the 24-hour pad weight test became popular.

CONCLUSIONS

There appears to be a higher completely dry rate with fewer subsequent tandem cuff additions with the perineal approach compared to the penoscrotal approach in a large multicenter study. This disparity may be explained by a more proximal AUS cuff placement in the perineal group compared to the penoscrotal group as evidenced by the larger cuff size of the perineal approach.

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