Perineal Approach for Artificial Urinary Sphincter Implantation Appears to Control Male Stress Incontinence Better Than the Transscrotal Approach

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Purpose: Traditionally cuff placement of an artificial urinary sphincter is done through a perineal approach. A new approach through a penoscrotal incision or transscrotal approach is reportedly more rapid and easier than the traditional incision. These 2 approaches were evaluated to determine which one controlled male stress urinary incontinence better.

Materials and Methods: We performed a retrospective chart review of 94 patients who underwent artificial urinary sphincter placement procedures from April 1987 to March 2004.

Results: A total of 126 artificial urinary sphincter cuffs (120 procedures, including double cuff placement in 6) were placed in 94 patients with 63 placed penoscrotally and 63 placed perineally. Of the double cuff placements 1 was perineal and 5 were transscrotal. In patients with a single initial or revision cuff the self-reported completely dry rate was 28.6% with the penoscrotal approach and 56.5% with the perineal approach ($p = 0.01$), while for initial cuffs only the dry rate was 28.0% and 56.7% for the penoscrotal and perineal approach, respectively ($p = 0.03$). Five of 28 patients (17.9%) with initial penoscrotal placement later underwent tandem cuff placement for continued incontinence, whereas only 1 of 32 (3.1%) with initial perineal placement later had a tandem cuff added ($p = 0.06$). There was no difference in the estimated failure-free survival (failure for any reason) of the device.

Conclusions: When the artificial urinary sphincter cuff is placed through a perineal approach, there appears to be a higher completely dry rate and fewer subsequent tandem cuff additions than when the artificial urinary sphincter cuff is placed through a penoscrotal incision.

Key Words: ureter; male; urinary sphincter, artificial; urinary incontinence; prostheses and implants

Since the first published article, in 1974 by Scott et al on AUS implantation to treat urinary incontinence, the traditional surgical procedure has involved a perineal incision.[1] Typically a lower abdominal incision is made to place the pressure regulating balloon and pump, and the perineal incision is made for cuff placement. This method has been successful for more than 30 years with reported patient satisfaction rates of up to 90% in some studies.[2,3] In their male patients receiving AUS cuffs at the bulbar urethra Venn et al reported a 92% continence rate at 10 years of followup.[4] In a study of 113 patients at a mean followup of 73 months Montague et al found that 73% were very satisfied (28%) or satisfied (45%) with the results of the procedure.[5] Nevertheless, a certain percent of patients with an AUS requires revision. In 2005 Raj et al reported that 90% of 119 patients with an AUS used 0 or 1 pad daily with primary implantation vs 82% with secondary implantation.[6] They also reported a product durability rate of 80% for primary and 88% for secondary implantation.

Recently there were several changes to the AUS, including the introduction of a pressure regulating balloon in the mid 1970s and in 1987 the narrow back cuff design.[7] Today the most popular device, the AMS800™, is the end result of many improvements. There have also been modifications of the surgery, including a double cuff for severe stress incontinence, cuff downsizing due to urethral atrophy and transcorporeal cuff placement in atrophy and erosion cases.[8,9]

Despite all of these changes the perineal approach has remained the surgical approach of choice. However, in 2003 Wilson et al presented a novel method of implantation using a single upper transverse scrotal incision.[10] All parts of the AUS could be placed via this incision and early results were encouraging. Of the 37 patients 25 (66%) were completely dry at a mean followup of 12 months and there was no difference in the complication rate at 12 months compared with that of the traditional method. In a 2006 outcome analysis of synchronous penile and sphincter prosthetic implants via a single scrotal incision Kendrici et al found that all 22 patients were using 1 pad or less daily at a mean followup of 17 months.[11]

Use of the transscrotal technique has been increasing since 2003 and some experts believe that there is no difference in functional outcome or mechanical survivability. Conversely critics believe that there is a difference in outcome between the perineal and transscrotal approaches. To our knowledge there has been no published study to date of functional outcomes and survivability comparing the trans-

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TABLE 1. *Preoperative variables by group*

Group	No. Pts	Mean Age at Surgery	Mean No. Pads/ Day (range)	No. RRP Stress Urinary Incontinence (%)
RS	17	63.3	4.0 (1.5–10)	16 (94.1)
RP	13	68.7	4.4 (2–10)	13 (100)
IS	31	70.5	5.2 (1–12)	19 (61.3)
IP	33	62.8	4.5 (2–10)*	19 (57.6)
Totals	94	66.3	4.7 (1–12)	67 (71.3)

* One patient who used a condom catheter and 1 who used a clamp plus pads not included in this average.

verse scrotal and perineal techniques. We present what is to our knowledge the first long-term study with more than 15 years of experience in a high volume of patients to compare the 2 approaches for the continence rate and mechanical survivability.

MATERIALS AND METHODS

We performed a retrospective chart review of 94 male patients undergoing AUS implantation and revision, as performed by 3 surgeons at 1 medical facility from April 1987 to March 2004. To our knowledge this included all consecutively performed surgeries at the medical facility. In 94 patients a total of 120 procedures were done with a total of 126 AUS cuffs placed, including double cuff placement in 6, on the bulbar urethra. Institutional review board approval was obtained for the study and all patients provided informed consent.

Standard preoperative evaluation included a history and physical examination, cystoscopy and urinalysis. Most patients underwent urodynamics. The causes of incontinence included RRP, combination RRP and radiotherapy, transurethral prostate resection and neurological injury or malformation. Surgical techniques for the perineal and transscrotal approaches have been described previously.[10,12]

Patient medical records and operative reports were reviewed for various demographic and preoperative variables, including patient age at implantation, etiology of incontinence, type of prior treatment for urinary incontinence and pads per day used preoperatively. Surgical variables that were recorded included the date of surgery, whether the surgery was initial implantation or revision, surgical approach (transscrotal or perineal) and any synchronous surgical procedure, including penile prosthesis implantation. The postoperative outcomes recorded from the chart review were the number of pads used per day if any, complications (infection/erosion, malfunction or atrophy), months to revision if applicable, revision type and total followup time in months. When applicable, failure was defined as that caused by any reason.

Nonparametric mechanical failure-free duration curves were calculated using the Kaplan-Meier product limit method.[13] Patients were separated into 2 groups and subgroups for analysis, including those undergoing primary implantation of an AUS with the perineal vs the transscrotal approach (group 1) and those undergoing revision/replacement of an AUS with the perineal vs the transscrotal approach (group 2). Subgroups were identified as IP, IS, RP and RS. Separate curves were estimated for each of the 4 patient subgroups and the 2 subgroup curves in each group were then compared using the log rank test.[13] Data management and analysis were performed using the Stata® statistical package, version 8.0.

RESULTS

Patients

The records of 94 male patients were reviewed for this study. Patients were classified into 4 categories based on the first procedure, including 17 (18.1%) and 13 (13.8%) for RS and RP, and 31 (33.0%) and 33 (35.1%) for IS and IP, respectively. Mean patient age at surgery in all groups was 66.3 years (range 30 to 94). In IS and IP mean age was 70.5 and 62.8 years, respectively ($p = 0.001$). Age in the revision subgroups was not significantly different. Mean preoperative pad use in all groups was 4.7 pads per day (range 1 to 12). All subgroups had statistically similar preoperative pad use per day. Table 1 lists preoperative details for each group.

Procedures

In 94 men a total of 126 AUS cuffs were placed at 120 procedures, including double cuff procedures in 6. Half or 63 of the 126 cuffs were implanted via a transverse scrotal incision and the remaining 63 were done via a perineal approach. Of the 120 procedures 64 (53.3%) were initial surgeries and 56 (46.7%) were revisions, while 62 (51.7%) were perineal and 58 (48.3%) were scrotal. The number of procedures per group was 33 in IP, 31 in IS, 29 in RP and 27 in RS.

Outcomes and Followup

Of the 92 procedures (76.7%) with known continence followup (28 had incomplete continence followup) 81 had a single cuff placed and the remaining 11 had double cuffs placed or a tandem cuff added. For initial implantations with a single cuff 7 of 25 patients (28%) receiving implants via the scrotal approach compared to 17 of 30 (56.7%) in the perineal groups were completely dry with no pad use ($p = 0.03$, table 2). When combining the initial and revision procedures for a single cuff, 10 of 35 patients (28.6%) who underwent scrotal placement compared to 26 of 46 (56.5%) who underwent perineal placement were completely dry

TABLE 2. *Postoperative completely dry and social continence rates for single cuff procedures, by group*

Group	No. Procedures With Adequate Followup	No. Completely Dry (%)	p Value	No. Socially Continent (%)	p Value
RS	10	3 (30.0)	0.19	5 (50.0)	0.09
RP	16	9 (56.3)		13 (81.3)	
IS	25	7 (28.0)	0.03	15 (60.0)	0.29
IP	30	17 (56.7)		22 (73.3)	
Totals	81	36 (44.4)		55 (67.9)	

TABLE 3. *Postoperative completely dry and social continence rates for all single and tandem/double cuff procedures by group*

Group	No. Procedures With Followup	No. Completely Dry (%)	p Value	No. Socially Continent (%)	p Value
RS	12	4 (33.3)	0.24	6 (50.0)	0.10
RP	22	12 (54.5)		17 (77.3)	
IS	28	10 (35.7)	0.11	18 (64.3)	0.46
IP	30	17 (56.7)		22 (73.3)	
Totals	92	43 (46.7)		63 (68.5)	

(p = 0.01). The completely dry rate for RS and RP was 30.0% (3 of 10 patients) and 56.3% (9 of 16), respectively (p = 0.19). Table 2 shows the socially continent rate, defined as 1 pad or less per day, in all groups undergoing single cuff placement. Table 3 lists the same characteristics in all patients in the study, that is those with a single and tandem/double cuff. The overall continence rate for all 92 procedures with known continence followup in this study was 46.7% and the overall socially continent rate was 68.5%.

The most common complication overall was AUS malfunction leading to leakage, which developed after 31 of the 109 procedures (28.4%). Leakage was defined as 2 or more pads used daily, or incontinence requiring further surgical treatment of the AUS, ie removal/replacement/cuff addition. Table 4 shows complications and management. In the initial scrotal and perineal groups tandem cuffs were later added in 17.9% and 3.1% of cases, respectively (p = 0.06, fig. 1). Estimated failure-free survival did not significantly differ with time between the initial implantation or revision groups (figs. 2 and 3).

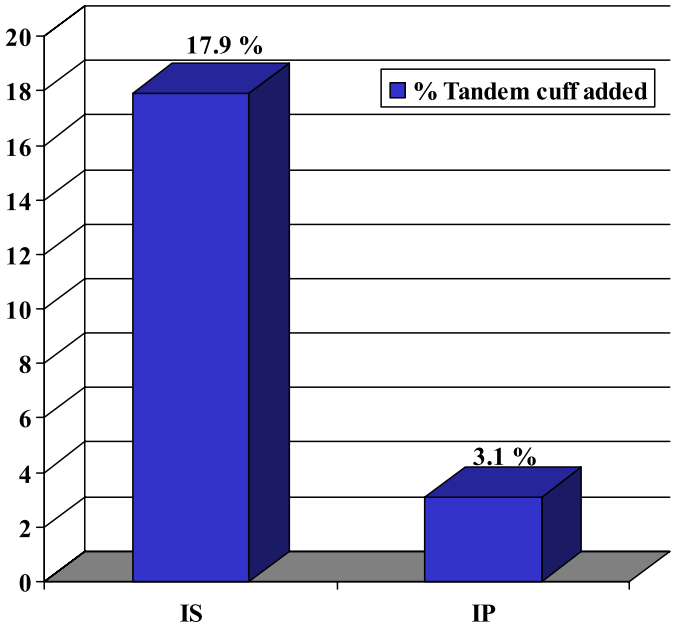

FIG. 1. Number of patients who later underwent tandem cuff addition after initial scrotal vs initial perineal approach (p = 0.06).

DISCUSSION

The AUS is considered the gold standard for moderate to severe stress urinary incontinence in men with a patient satisfaction rate of 75% to 90%.[1–5] After several generations the current model AMS800 was introduced in 1983 and, until the recent impregnation with antibiotics of the pump and cuff, it remained relatively unchanged. Conversely during the last 20 years in efforts to improve continence outcomes a number of novel surgical techniques have been used, specifically a double cuff for severe stress incontinence, cuff downsizing for urethral atrophy and transcorporeal cuff placement in atrophy and erosion cases.[8,9]

However, the perineal surgical approach remained unchanged for almost 30 years until Wilson et al introduced the single incision transscrotal approach.[10] Initial reports suggested that this technique produces results similar to those of the perineal approach with respect to completely dry and complication rates in patients with a followup of 12 months. Although this surgical method has increased in use since its creation, to our knowledge there have been no published studies comparing the 2 approaches in regard to product durability and the completely dry rate. Our results are the first long-term high volume study comparing the perineal and transscrotal surgical approaches for AUS implantation.

The term social continence has ranged in use from 0 to 2 pads per day, although it is more commonly thought to mean 1 pad or less per day.[14,15] In this study social continence was defined as 1 pad or less per day. The overall completely dry rate in all patients with known followup in the current study was 47%, while 69% were socially continent. Similar results for dry and social continence rates were reported by Lai et al in 218 patients (35% and 69%),[16] Gousse et al in 71 (27% and 59%)[17] and Montague et al in 113 (64%)[5] (social continence rate only).

Based on 81 procedures with a single cuff placed we found that 10 of the 35 patients (28.6%) who underwent scrotal placement were completely dry and 26 of the 46 (56.5%) who underwent perineal placement were completely dry (p = 0.01). By further stratifying the scrotal and perineal

TABLE 4. *Postoperative complications and management by group*

No.	RS (%)	No. RP (%)	p Value	IS	IP	p Value	Totals
Postop complications:	21	28		28	32		109
Malfunction	4 (19.0)	11 (39.3)	0.13	9 (32.1)	8 (25.0)	0.54	32 (29.4)
Erosion/infection	11 (52.4)	8 (25.0)	0.05	2 (7.1)	6 (18.8)	0.19	27 (24.8)
Urethral atrophy	1 (4.8)	1 (3.6)	0.84	0	4 (12.5)	0.05	6 (5.5)
Totals	16 (76.2)	20 (71.4)		11 (39.3)	18 (56.3)		65 (59.6)
Revision type:							
Revision	8 (38.1)	8 (28.6)	0.48	2 (7.1)	8 (25.0)	0.06	26 (23.9)
Removal	4 (19.0)	9 (32.1)	0.30	2 (7.1)	12 (37.5)	0.005	23 (21.1)
Tandem cuff added	2 (9.5)	4 (14.3)	0.61	5 (17.9)	1 (3.1)	0.06	12 (11.0)
Totals	14 (66.7)	21 (75.0)		9 (32.1)	21 (65.6)		65 (59.6)

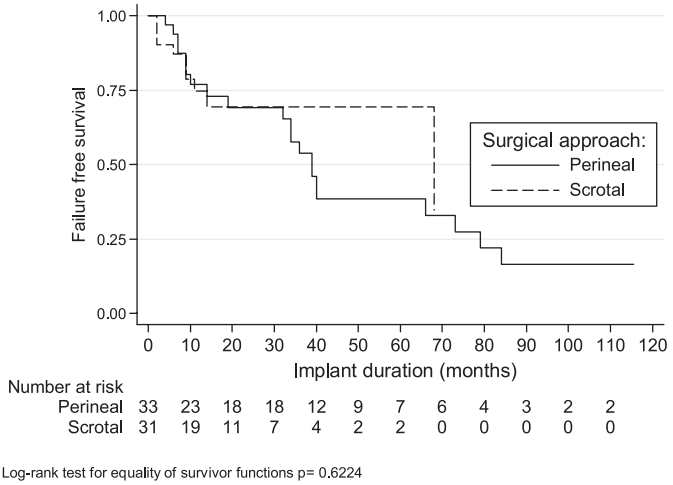

FIG. 2. Kaplan-Meier product limit estimated failure-free survival of initial implants stratified by surgical approach.

procedures into revision and initial implants we found that all comparisons of completely dry rates in patients with single cuffs favored the perineal approach (table 3). Moreover, when including the fact that IP patients had longer followup with better outcomes than IS patients, this makes an even stronger argument that the perineal approach should be the incision of choice for surgeons who can perform the 2 approaches with equal skill.

Postoperative complications between the groups were similar with 2 exceptions. The rate of infection/cuff erosion was higher in the revision scrotal group vs that in the revision perineal group (52% vs 25%, p = 0.05), while the rate of urethral atrophy was higher in the initial perineal group vs that in the initial scrotal group (12.5% vs 0%, p = 0.05). However, urethral atrophy required at least 3 years to develop and with the much shorter followup in the IS group this was not unexpected. Our results regarding the complication rate are similar to those of Venn et al, who reported a 66% revision/removal rate for male bulbar urethral cuffs.[4] Revisions in this study were defined as procedures that ended with a working device in place with tandem cuff additions made separate from this designation. With respect to product durability, Kaplan-Meier curves comparing perineal vs transscrotal approaches for initial implants and revisions did not show any significant difference.

In general the transscrotal approach is supported by several points. Most urologists who have used each technique would agree that this method is more rapid and easier. It involves only 1 incision to place all parts of the AUS, whereas the classic perineal approach requires 2 separate incisions, including 1 for the cuff and the other for pump and reservoir placement. However, recently one of us began to place the entire AUS device through a single perineal incision with pressure regulating balloon placement done similarly to the blind reservoir penoscrotal placement of an IPP. In this single perineal incision approach the pump is placed in a subdartos pouch in the scrotum from below, which is the exact opposite of transscrotal pump placement. With this direct vision subdartos pouch method there is no issue with pump migration using either approach.

Another advantage to the transscrotal approach is that IPPs can be placed at the same time through a single incision.[11] Thus, due to the familiarity of the IPP penoscrotal approach more surgeons are comfortable with this technique. In fact the number of AUSs placed per year, which has been stable for 10 years, increased by about 50% with the creation of the new transscrotal approach for AUS placement. In addition, as stated, there do not appear to be any high riding pumps after transscrotal AUS pump placement, whereas that is a well-known complication of the traditional 2 incision perineal approach.

During the transscrotal approach it has been argued that the urethra is more easily manipulated and one can perform posterior dissection better because the urethra is not under tension.[10] However, the advantage of tension-free dissection may be compromised by a distal urethral AUS location. Some investigators argue that the transscrotal method cannot anatomically place the AUS at the proximal bulbar urethra because it does not divide the bulbospongiosus muscle.[18] Instead, it is placed more distal on the thinning urethra, which may lead to more revisions due to loosely fitting cuffs and urethral atrophy compared to placement around the more robust proximal bulb approached via the perineum.

Despite all of the surgical advantages of the transscrotal technique it appears inferior to the perineal approach with respect to completely dry and social continence rates according to our study. This observation along with the fact that each approach has similar failure-free product durability and complication rates makes the argument to use the perineal approach when performing AUS implantation. In addition, the perineal approach is supported by numerous studies from multiple centers with good results and long-term followup.[2,5,15,17]

There were several limitations in the design and outcome analysis of this study that could be improved in future studies. The study was retrospective and it would benefit from a prospective, randomized trial evaluating the same outcomes. Variables such as operative time and perioperative blood loss were not recorded. Hospital charts were no longer available to obtain that information. This also affected how we measured AUS success, that is by patient pad use. In a recent study the 24-hour pad weight test was shown to more closely correlate with urinary leakage than

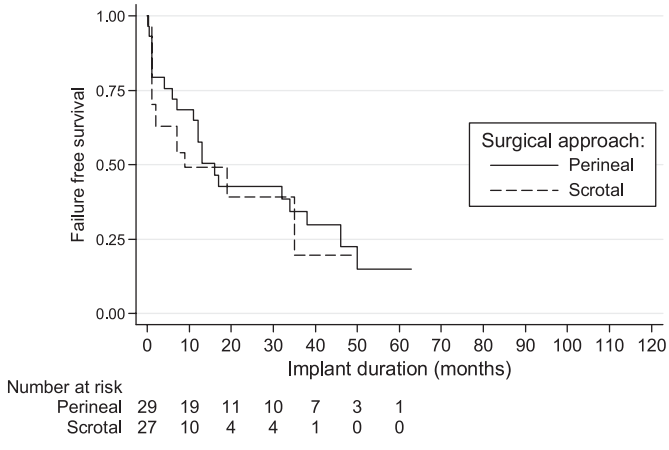

FIG. 3. Kaplan-Meier product limit estimated failure-free survival of revised implants stratified by surgical approach.

patient reported pad use.[19] 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] Regardless, most procedures in this study were done before the 24-hour pad weight test became popular. In conclusion, when the AUS cuff is placed through a perineal approach, there appears to be a higher completely dry rate and fewer subsequent tandem cuff additions than when the AUS cuff is placed through a transscrotal incision.

Abbreviations and Acronyms

AUS	=	artificial urinary sphincter
IP	=	initial perineal group
IPP	=	inflatable penile prosthesis
IS	=	initial scrotal group
RP	=	revision perineal group
RRP	=	radical prostatectomy
RS	=	revision scrotal group

REFERENCES

1. Scott FB, Bradley WE and Timm GW: Treatment of urinary incontinence by an implantable prosthetic urinary sphincter. J Urol 1974; **112:** 75.
2. Fishman IJ, Shabsigh R and Scott FB: Experience with the artificial urinary sphincter model AS800 in 148 patients. J Urol 1989; **141:** 307.
3. Gundian JC, Barrett DM and Parulkar BG: Mayo Clinic experience with use of the AMS800 artificial urinary sphincter for urinary incontinence following radical prostatectomy. J Urol 1989; **142:** 1459.
4. Venn SN, Greenwell TJ and Mundy AR: The long-term outcome of artificial urinary sphincters. J Urol 2000; **164:** 702.
5. Montague DK, Angermeier KW and Paolone DR: Long-term continence and patient satisfaction after artificial sphincter implantation for urinary incontinence after prostatectomy. J Urol 2001; **166:** 547.
6. Raj GV, Peterson AC, Toh KL and Webster GD: Outcomes following revisions and secondary implantation of the artificial urinary sphincter. J Urol 2005; **173:** 1242.
7. Petrou SP, Elliott DS and Barrett DM: Artificial urethral sphincter for incontinence. Urology 2000; **56:** 353.
8. Brito CG, Mulcahy JJ, Mitchell ME and Adams MC: Use of a double cuff AMS 800 urinary sphincter for severe stress incontinence. J Urol 1993; **149:** 283.
9. Guralnick ML, Miller EA, Toh KL and Webster GD: Transcorporeal artificial urinary sphincter cuff placement in cases requiring revision for erosion and urethral atrophy. J Urol 2002; **167:** 2075.
10. Wilson SK, Delk JR, Henry GD and Siegel AL: New surgical technique for sphincter urinary control system using upper transverse scrotal incision. J Urol 2003; **169:** 261.
11. Kendrici M, Gupta S, Shaw K, Morey A, Jones L, Hakim L et al: Synchronous prosthetic implantation through a transscrotal incision: an outcome analysis. J Urol 2006; **175:** 2218.
12. Scott FB: The artificial urinary sphincter: experience in adults. Urol Clin North Am 1989; **16:** 105.
13. Lee E: Statistical Methods for Survival Data Analysis, 2nd ed. New York: Wiley 1992; pp 67–78, 109–112.
14. Gnessin E, Livne PM, Baniel J and Gillon G: Continence and quality of life assessment after artificial urinary sphincter implantation. Isr Med Assoc J 2004; **6:** 592.
15. ter Meulen PH, Zambon V, Kessels AG and van Kerrebroeck PE: Quality of life, functional outcome, and durability of the AMS 800 artificial urinary sphincter in patients with intrinsic sphincter deficiency. Urol Int 71; **55:** 2003.
16. Lai HH, Hsu EI, The BS, Butler EB and Boone TB: 13 years of experience with artificial urinary sphincter implantation at Baylor College of Medicine. J Urol 2007; **177:** 1021.
17. Gousse AE, Madjar S, Lambert M and Fishman IJ: Artificial urinary sphincter for post-radical prostatectomy urinary incontinence: long-term subjective results. J Urol 2001; **166:** 1755.
18. Flynn BJ and Webster GD: Evaluation and surgical management of intrinsic sphincter deficiency after radical prostatectomy. Rev Urol 2004; **6:** 180.
19. Dylewski DA, Jamison MG, Borawski KM, Sherman ND, Amundsen CL and Webster GD: A statistical comparison of pad numbers versus pad weights in the quantification of urinary incontinence. Neurourol Urodyn 2007; **26:** 3.

EDITORIAL COMMENT

The surgical advantages of the transscrotal implantation of AUS cuffs have caused many implanters to adopt this approach. These authors present some important data relative to this approach, although it is sometimes difficult to follow.

This study denotes a statistically significant better outcome for complete dryness in patients in whom initial single cuff placement was performed transperineally in comparison with transscrotal placement. This was also found in the combined group of initial and revision procedures for single cuff placement. The erosion/infection rate was lower for transperineally placed cuffs and the urethral atrophy rate was higher in this group, although the overall number of patients experiencing atrophy was small. Differences in social continence rates did not attain statistical significance.

This study presents some compelling arguments to question the use of this approach for cuff placement. As the authors noted, followup in the transscrotal group is much shorter than in the transperineal group. I hope that they continue to follow this cohort and update their progress in the future.

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REPLY BY AUTHORS

The transscrotal approach for implantation of the AUS cuff is faster and easier than the perineal approach for most urologists. Nevertheless, the results in this cohort of patients from the first group to publish this technique appear to show an advantage with the perineal approach in terms of completely dry and infection/erosion rates. Advocates of the transscrotal approach claim to be placing the AUS cuff in the same location as with the perineal approach and achieving similar incontinence rates.

Since the current findings were evaluated, a 5 center study group has been formed to obtain a larger number of patients and longer followup. We are also comparing different cuff sizes with each approach and plan to submit our findings in the near future.