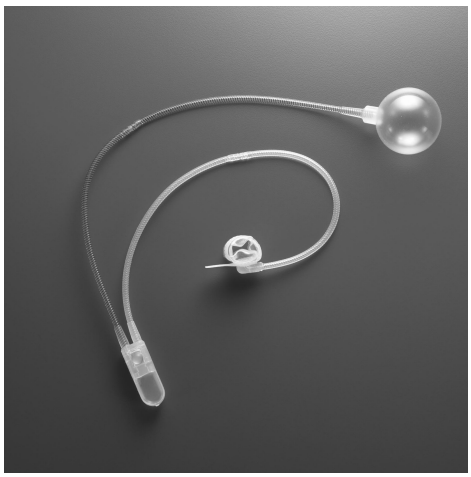
AMS 800™ Clinical Article Summaries*



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AMS 800 Clinical Article Summaries*

AMS 800 Journal Articles

Study & Publication	Authors	Number of Patients	Key Findings
Cost And Time Benefits Of Dual Implantation Of Inflatable Penile And Artificial Urinary Sphincter Prosthetics By Single Incision	C. L. Sellers A.F. Morey L.A. Jones	128	• 92 inflatable penile prostheses (IPP's) • 21 artificial urinary sphincters (AUS's) • 15 combined IPPs/AUSs • 16 months median follow up (range 4-31) • Wilson single incision upper transverse scrotal technique used • Dual implantation in a single-stage procedure reduced (24.7%) operative time ($p<0.05$, mean 113 minutes) compared with individual implant procedures (IPP, average of 78 minutes and AUS, average of 72 minutes, total 150 minutes) • Dual implantation represents an approximate $7000 cost savings (dual IPP/AUS $25,000 versus metachronous IPP and AUS $32,000) Complications: • None reported
Outcomes Following Revisions And Secondary Implantation Of The Artificial Urinary Sphincter, J Urol 2005	G. Raj A. Peterson K. Toh G. Webster	554 males	• 80% 5-year durability in patients with primary AUS implantation • 88% 5-year durability in patients with secondary AUS implantation • 90% continence outcomes (0-1 pad/day) in patients with primary AUS implantation • 82% continence outcomes (0-1 pad/day) in patients with secondary AUS implantation • 89% baseline continence in patients with secondary and tertiary AUS revisions Complications: • 25.2% failure due to mechanical complications in patients undergoing 2nd AUS implantation • 73.9% failure due to nonmechanical complications (urethral cuff atrophy) in patients undergoing 2nd AUS implantation • 1.74% institutional erosion and infection rate for both primary and secondary procedures • 0.46% institutional erosion and infection rate for primary AUS implantation • 5.0% institutional erosion and infection rate for secondary AUS implantation
A National Survey Of Urinary And Health Related Quality Of Life Outcomes In Men With An Artificial Urinary Sphincter For Post-Radical Prostatectomy Incontinence, J Urol 2003	B. Dalkin H. Wessells H. Cui	581 males	• 289 patients from 1995 cohort results (average 5 year followup) • 292 patients from 1999 cohort (average 2 year followup) • 83% success rate (dry defined as 2 pads or less a day) Complications: • 1995 Cohort • 28% revision rate • 1999 Cohort • 16% revision rate

AMS 800 Journal Articles *(continued)*

Study & Publication	Authors	Number of Patients	Key Findings
Comparison Of Outcomes After Single Or Double-Cuff Artificial Urinary Sphincter Insertion, Urology 2003	R. O'Connor G. Gerber D. Avila A. Chen G. Bales	56 males	• 28 double cuff patients • 28 single cuff patients • 41.3 months average followup (10-66) single-cuff patients • 21.2 months average followup (6-55) double-cuff patients • 11% of single cuff patients used 0 pad/day • 61% of single cuff patients used 0-1 pad/day • 28% of single cuff patients used > 1 pad/day • 43% of double cuff patients used 0 pad/day • 43% of double cuff patients used 0-1 pad/day • 14% of double cuff patients used > 1 pad/day Complications: • Of the 5 complications in single cuff patients • 40% tubing leak • 40% urethral erosion • 20% exposed tubing • 0 urethral stricture • 0 cuff leak • Of the 4 complications in double cuff patients: • 50% tubing leak • 0 urethral erosion • 25% exposed tubing • 25% urethral stricture • 0% cuff leak
New Surgical Technique For Sphincter Urinary Control System Using Upper Transverse Scrotal Incision, J Urol 2003	S. Wilson J. Delk, II G. Henry A. Siegel	37 males	• 12 months mean followup (6-30) • 66% patients are dry with 0/day • 34% of patients wear 1/day • No patient uses more than 1/day • Operative time for AUS placement was less than 1 hour in all cases. Average operative time was 35 minutes (range 20 to 52) in the 25 initial cases • No patient reported sensations of discomfort from the scrotally placed cuff • No patient to date has reported leakage from cuff compression, late cuff erosion or return of incontinence (urethral atrophy or mechanical failure) • The transscrotal technique affords some advantages over the dual incision perineal approach: – The technique requires only 1 incision – Implantation can be performed faster than the standard 2-incision approach – The scrotal incision technique is performed with the patient supine, so the urethra is more mobile and this mobility facilitates posterior dissection • The pump is placed virtually under direct vision and the ostium of its tunnel is closed with a purse-string suture, there were no malpositioned or high riding pumps in the series Complications: • 5% cuff erosion

AMS 800 Journal Articles *(continued)*

Study & Publication	Authors	Number of Patients	Findings
Salvage Procedure For Infected Noneroded Artificial Urinary Sphincters, J Urol 2002	D. Bryan J. Mulcahy G. Simmons	8 males	• 8 patients underwent a total of 9 salvage operations • 33 months mean followup (5-66 months) • Salvage procedure was performed within 5 days of the diagnosis of device infection • 37.5% of patients had concurrent inflatable penile prosthesis salvage. This situation did not adversely affect the functioning of either device • 87% of patients were free of infection with a functioning AUS as most recent followup
Artificial Urinary Sphincter For Post-Prostatectomy Incontinence In Men Who Had Prior Radiotherapy: A Risk And Outcome Analysis, J Urol 2002	M. Gomha T. Boone	86 males	• 32±23 months mean followup (2-83 months) • 58 patients who did not receive prior radiation therapy (group 1) • 60% wore 0-1 pad/day • 26% wore 1-2 pads/day • 14% wore 2+ pads/day • 88% of patients rated a 4 or greater their improvement after AUS on visual analog scale (range 0-5) • 86% of patients rated their satisfaction 4 or greater • 94% of patients would recommend the AUS to a friend • 90% of patients would undergo AUS implantation again • 28 patients who did receive previous pelvic radiation therapy (group 2) • 64% wore 0-1 pad/day • 14% wore 1-2 pads/day • 22% wore 2+ pads/day • 96% of patients rated a 4 or greater their improvement after AUS on visual analog scale (range 0-5) • 91% of patients rated their satisfaction 4 or greater • 96% of patients would recommend the AUS to a friend • 96% of patients would undergo implantation again Complications: • Group 1 (49 patients) • 4% pain (48 pts in this group) • 6% straining • 47% post-op urgency with or without urgency incontinence • 35% daily leak • 35% damp, wet, soaked pads • 14% urethral atrophy • 2% erosion • 7% infection • 3% leakage in device • 0 pump malfunction • 3% pump malposition • 2% superficial abscess • 13.8% 1 reoperation • 8.6% 2 reoperations • 2% 3 reoperations • 22.4% total reoperations

continued on next page

AMS 800 Journal Articles *(continued)*

Study & Publication	Authors	Number of Patients	Key Findings
			Group 2 (23 patients) • 4% pain • 0 straining • 43% postop urgency with or without urge incontinence • 22% daily leak • 48% damp, wet, soaked pads • 14% urethral atrophy • 7% erosion • 0 infection • 0 leakage in device • 4% pump malfunction • 0 pump malposition • 0 superficial perineal abscess • 18% 1 reoperation • 7% 2 reoperations • 0 3 reoperations • 25% total reoperations
Transcorporal Artificial Urinary Sphincter Cuff Placement In Cases Requiring Revision For Erosion And Urethral Atrophy, J Urol 2002	M. Guralnick E. Miller K. Toh G Webster	31 males	• A novel technique for distal cuff placement using transcorporal dissection that leaves corporal tunica albuginea on the dorsal surface of the urethra, allowing for its safer mobilization and adding to its bulk • 17 months mean followup (2-86 months) • 84% of patients had mild or no stress type incontinence requiring 0 to 1 pad daily • 96% of patients were satisfied with the level of continence • There was no erosion or infection of the transcorporal cuffs • 90% of patients had the original transcorporal cuff in situ Complications: • 3% of patients the transcorporal cuff was replaced due to injury from another procedure • 6% of patients had revision and replacement of the transcorporal cuff due to mechanical malfunction • The only serious drawback to transcorporal AUS cuff placement relates to erectile dysfunction. Because the corporal bodies are purposely violated, there is a risk of postoperative erectile dysfunction. Generally, we have observed that patients with post-prostatectomy incontinence are more concerned about incontinence than about erectile dysfunction

Cost And Time Benefits Of Dual Implantation Of Inflatable Penile And Artificial Urinary Sphincter Prosthetics By Single Incision

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Urology 2005 v. 65 p. 852-853

Objectives: To evaluate the efficiency, safety, and cost-effectiveness of synchronous prosthetic treatment of male urinary incontinence and impotence using a single transverse scrotal incision.

Methods: A total of 92 inflatable penile prostheses (IPPs), 21 artificial urinary sphincters (AUSs), and 15 combined IPPs/AUSs were implanted in 128 men at Brooke Army Medical Center and the University of Texas Health Science Center at San Antonio. The operative times and outcomes were compared among three groups (group 1, IPP; group 2, AUS; and group 3, dual IPP/AUS). We performed cost estimates of synchronous versus two-stage implant procedures.

Results: Dual implantation in a single-stage procedure significantly reduced (24.7%) the operative time ($P<0.05$, mean 113 minutes) compared with the total time for the individual procedures (IPP, average of 78 minutes; AUS, average of 72 minutes; total 150 minutes).

The median patient follow-up was 16 months (range 4 to 31), and no prosthetic infections or erosions were observed in this series. Using cost estimates provided by AMS Health Care Affairs, dual implantation represents an approximate $7000 cost savings (dual IPP/AUS $25,000 versus metachronous IPP and AUS $32,000).

Conclusion: Simultaneous surgical treatment of impotence and incontinence through a single incision is safe and efficient—minimizing risk and maximizing patient satisfaction. The technical ease of synchronous penile and urethral prosthetic implantation provides substantial time and cost savings.

Table I: Comparison of mean operative times

Procedure	n	Mean Operative Time (min)	SD	Range (min)
IPP	92	78	24	45-125
AUS	21	72	22	35-155
Dual IPP/AUS	15	113	33	72-162

KEY: IPP = inflatable penile prosthesis; AUS = artificial urinary sphincter.

Outcomes Following Revisions And Secondary Implantation Of The Artificial Urinary Sphincter

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Journal of Urology Apr 2005 v. 173 (4) p. 1242-1245

Purpose: Durable success with the artificial urinary sphincter (AUS) is common but device revision and replacement are often needed for various reasons. We examined indications and outcomes following these secondary procedures with comparisons to outcomes after primary procedures.

Materials and Methods: The medical records of all patients undergoing primary and secondary bulbar urethral AUS implantation and revision from January 1990 to September 2002 were reviewed for various demographic and surgical variables. Female patients and males with bladder neck cuffs were excluded from study cohort.

Results: Of 554 men undergoing AUS implantation or revision 119 (21.4%) underwent a total of 159 secondary procedures. Reasons for revision were mechanical failure in 31 cases (25.2%) and nonmechanical failure in 88 (73.9%). The latter included recurrent incontinence due to urethral atrophy in 63 cases (52.9%) and erosion in 21 (17.6%). Total device replacement was performed in 75 cases (47.2%). Of 119 patients undergoing secondary implantation 91 (76.5%) needed no additional surgical intervention, while 28 (23.5%) required a total of 40 surgical revisions for new mechanical (15 or 37.5%) and nonmechanical (25 or 62.5%) problems. Five-year durability outcomes for primary and secondary AUS implantation were comparable at 80% and 88%, respectively. Similarly excellent continence outcomes (0 to 1 pad daily) were noted in 90% and 82% of patients undergoing primary and secondary AUS implantation, respectively. Secondary and tertiary AUS revisions resulted in the restoration of baseline continence in 106 cases (89%).

As with any repeat operations, secondary AUS implantation is perceived to have higher complication rates and worse outcomes. However, our data indicates that a good outcome with a low complication rate for secondary implantations is achievable, provided that an appropriate strategy for dealing with limited healthy urethral tissue is adopted, combined with meticulous attention to sterile technique.

Fig. 1. Kaplan-Meier curves demonstrate durability of primary and secondary AUS implantations

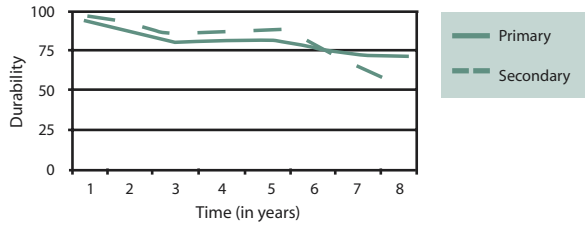
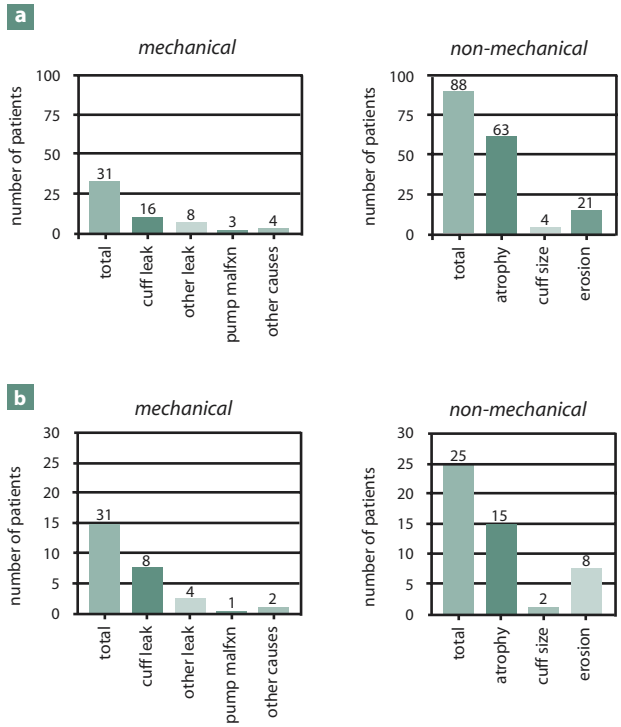


Fig. 2. Etiology of revision of primary (a) and secondary (b) AUS implantation. *malfxn*, malfunction



A National Survey Of Urinary And Health Related Quality Of Life Outcomes In Men With An Artificial Urinary Sphincter For Post-Radical Prostatectomy Incontinence

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Journal of Urology Jan 2003 v. 169(1) p. 237-239

Purpose: We determine health related quality of life and urinary outcomes of men undergoing implantation of an artificial urinary sphincter for post-radical prostatectomy incontinence.

Materials and Methods: Through a data base provided by American Medical Systems, we mailed the UCLA Prostate Cancer Index to men who underwent artificial urinary sphincter implantation during 6-month intervals in 1995 and 1999, providing 5 and 2-year followup data, respectively.

Results: Of the anonymous questionnaires 36% were returned from the 1995 cohort and 45% from the 1999 cohort. Age adjusted mean scores for the 8 health related quality of life domains were comparable in both groups. Urinary function and bother scores were worse in the 1995 cohort compared to the 1999 group (40 and 48 versus 53 and 58, respectively, p <0.001), with pad use of 97% and 83% respectively. Revision rates were 16% at 2 years and 28% at 5 years after implantation.

Conclusions: We administered the UCLA Prostate Cancer Index anonymously to men identified through a data base provided by American Medical Systems. This national survey of men 2 and 5 years after artificial sphincter implantation for postradical prostatectomy incontinence determined continence results that differed considerably from many reported single institution studies. Significantly higher revision rates, and lower age adjusted urinary function and bother scores were noted 5 years compared to 2 years after implantation. However, despite these urinary differences, no differences in general health related quality of life were noted between the 2 cohorts. The vast majority of men continue to use protective undergarments after sphincter implantation, although urinary function and degree of pad use may be considerably improved from pre-implantation status. These results speak strongly for prospective studies of all urinary incontinence treatments after radical prostatectomy to determine accurately outcomes that will aide in counseling patients who elect to undergo these treatments.

Table I: Age adjusted health related quality of life scale score for general urinary, sexual and bowel domains, and incontinence questions

Category	1995	1999
Mean age (SD)	74 (8)	70 (7)
Mean physical function (SD)	73 (27)	76 (26)
Mean physical role (SD)	59 (42)	60 (44)
Mean emotional role (SD)	74 (39)	72 (40)
Mean energy (SD)	58 (21)	56 (22)
Mean emotional well-being (SD)	77 (18)	76 (19)
Mean social function (SD)	79 (25)	81 (25)
Mean pain (SD)	73 (26)	75 (24)
Mean general health (SD)	64 (21)	63 (23)
Mean urinary function (SD)	40 (22)	53 (25)*
Mean urinary bother (SD)	48 (32)	59 (24)*
Mean sexual function (SD)	22 (18)	9 (11)*
Mean sexual bother (SD)	24 (35)	29 (37)
Mean bowel function (SD)	79 (21)	81 (18)
Mean bowel bother (SD)	72 (32)	77 (29)*
% Pad use	97	83*
% Incontinence		
Mild	38	59*
Moderate	37	32
Severe	24	9*

Results are expressed as a numerical score ranging from 0 to 100 with 100 being the highest possible response
**Difference is statistically significant (p<0.001).*

Comparison Of Outcomes After Single Or Double-Cuff Artificial Urinary Sphincter Insertion

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Urology Oct 2003 v. 62(4) p. 723-726

Objectives: To assess the effectiveness and complications associated with single and double-cuff artificial urinary sphincter (AUS) implantation for postprostatectomy stress urinary incontinence.

Methods: A retrospective study of 56 men with postprostatectomy stress urinary incontinence who underwent either single (28 patients) or double (28 patients) cuff AUS placement was performed. Patients in each cohort were matched on the basis of preoperative pad use, risk factors for complications, and age. Patient selection was blinded relative to outcome. Continence, quality of life, and complications were assessed using the Incontinence Impact Questionnaire Short Form (IIQ-7), postoperative pad use, and chart review.

Results: The mean age was 67 years for each group. Daily pad use decreased from 7.7 to 1.1 in patients treated with a single-cuff AUS and from 7.8 to 0.7 in patients with a double-cuff AUS (P =0.25). Complete continence (0 pads daily) was reported in 3 (11%) of 28 men with single-cuff and 12 (43%) of 28 men with double-cuff sphincters (P 0.008). The IIQ-7 scores improved from 14.8 to 3.1 after single-cuff placementand from 16.3 to 2.5 after double-cuff placement (P =0.03). With an average follow-up of 41.3 and 21.2 months for the single and double-cuff cohorts, respectively, five complications were reported in the single cuff recipients and four in the double-cuff patients.

Conclusion: Using a retrospective, matched-cohort study, we have demonstrated improved rates of complete continence in men with postprostatectomy SUI treated with a double-cuff AUS compared with those receiving a single-cuff device. In addition, greater improvement in the IIQ-7 was seen in the double-cuff group. Finally, we did not observe an increased complication rate with the use of a tandem cuff. These results may indicate an overall improved outcome using a double-cuff AUS. Additional study is needed to confirm the relative success of the double-cuff device.

Table II: Daily pad usage in men with single and double-cuff artificial urinary sphincters

Pad Use	Single Cuff	Double Cuff	*P* Value
Mean before AUS	7.7	7.8	0.76
Mean after AUS	1.1	0.7	0.10
Difference	6.6	7.1	0.25
0 pad/day	3/28 (11)	12/28 (43)	0.008
0-1 pad/day	17/28 (61)	12/28 (43)	0.20
> 1 pad/day	8/28 (28)	4/28 (914)	0.22

KEY: AUS = artificial urinary sphincter.
Numbers in parentheses are percentages.

Table III: Incontinence Impact Questionnaire Short Form* results

Has Urine Leakage Affected Your	Before Single-Cuff AUS	After Single-Cuff AUS	Before Double-Cuff AUS	After Double-Cuff AUS
Household activities?	1.4	0.3	1.6	0.2
Physical recreation?	1.9	0.4	2.5	0.5
Entertainment?	2.1	0.4	2.3	0.2
Travel by car >30 min?	2.3	0.5	2.4	0.3
Social activities?	2.3	0.5	2.5	0.4
Emotional health?	2.4	0.5	2.4	0.4
Feeling frustrated?	2.4	0.5	2.6	0.5
Total	14.8	3.1	16.3	2.5

KEY: AUS = artificial urinary sphincter.
** Score: 0 = not at all; 1 = slightly; 2 = moderately; 3 = greatly.*

New Surgical Technique For Sphincter Urinary Control System Using Upper Transverse Scrotal Incision

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Journal of Urology Jan 2003 v. 169(1) p. 261-264

Traditional implantation of the AMS Sphincter 800 Urinary Control System (American Medical Systems, Minnetonka, Minnesota) requires 2 incisions. The cuff is placed via a perineal incision, and the pressure regulating balloon and pump are placed through a separate suprapubic incision. We describe a novel implantation of all the artificial urinary sphincter components using a single upper scrotal incision. The scrotal incision allows excellent access to the proximal bulbar urethra and retropubic and subdartos spaces, and leaves the bulbocavernosus muscle intact.

Materials and Methods: A total of 37 patients have undergone artificial urinary sphincter implantation using the new operative technique for revisions or reimplantations of a sphincter previously removed for infection/erosion (12) or as an initial procedure (25). In 9 of the 25 patients and 2 of the 12 dual implantation of a 3-piece penile prosthesis through the same incision was performed.

Results: All patients are using the devices. Of the patients 66% are completely dry with no pad use and the remainder use 1 pad for accident prevention. Operative time was reduced due to easier exposure of the urethra and a second incision for placement of the pressure regulating balloon was not necessary. Followup at 1 year shows no difference in complication rate with the single incision technique compared to the traditional method.

Because the pump is placed virtually under direct vision with the transscrotal approach and the ostium of its tunnel is closed with a purse-string suture, there were no malpositioned or high riding pumps in our series.

Operative time for artificial urinary sphincter placement was less than 1 hour in all cases. Average operative time was 35 minutes (range 20 to 52) in the 25 initial cases.

Conclusion: The high transverse scrotal incision allows excellent access to the proximal bulbar urethra, and retropubic and subdartos spaces, permitting implantation of all 3 components through a single incision. Transscrotal implantation of the AMS Sphincter 800 Urinary Control System using only 1 incision offers significant advantages over the traditional 2-incision method for sphincter revisions and reimplantations of sphincters previously removed for infection/erosion. Early results also show an advantage in patients without previous sphincter surgery. The surgery in both groups is easier and quicker. The continence results are similar for both methods. Long-term followup and more implantations are needed to determine if the complication rate remains acceptable.

Salvage Procedure For Infected Noneroded Artificial Urinary Sphincters

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Journal of Urology Dec 2002 v. 168(6) p. 2464-2466

Purpose: We report our experience with removal, antiseptic irrigation and immediate reimplantation of infected noneroded artificial urinary sphincters.

Materials and Methods: From April 1996 to October 2000, 8 patients with an infected artificial urinary sphincter underwent a total of 9 salvage operations. All patients underwent cystoscopy before salvage to ensure nonerosion of the sphincter cuff. All previously implanted material was removed, the wounds were copiously irrigated according to a 7 solution protocol and an identical new system was implanted. All patients were discharged home the following morning on oral antibiotics.

Results: Followup was 5 to 66 months (mean 33). The predominant organisms cultured at salvage were gram-positive cocci. Time from implantation to salvage was from 2 weeks to 64 months (mean 13.7 months). Prostatectomy was the etiology of incontinence in all except 1 case. In 5 of the 8 men a double cuff system was placed and 3 underwent concurrent 3-piece inflatable penile prosthesis salvage. The salvage procedure was done twice in 1 patient 5 months apart. The system was removed 16 months later secondary to urethral erosion. At the most recent followup the other 7 patients were free of infection with a functioning artificial urinary sphincter.

Conclusions: Infection without erosion of artificial urinary sphincters mandates removal of the original prosthetic parts. This previously devastating complication and return to incontinence can be avoided by a salvage procedure. Single and double cuff salvage can be performed with an overall success rate of 87% in this series. The usual offending organisms are grampositive skin flora. An associated inflatable penile prosthesis does not prohibit salvage, although the 2 devices must be salvaged simultaneously.

Appendix 1: Salvage Protocol*

1) Remove all prosthetic parts and foreign material
2) Irrigate wound with 7 antiseptic solutions
3) Change gowns, gloves, surgical drapes and instruments
4) Insert new prosthesis
5) Close wounds with no drains or catheters
6) Treat with oral antibiotics for 1 month

Appendix 2: Antiseptic Irrigating Solutions*

1) Antibiotic irrigation (bacitracin and gentamicin in 0.9% normal saline)
2) Half strength hydrogen peroxide
3) Half strength povidine-iodine
4) Pressure irrigation with 1 gm. vancomycin and 80 mg. gentamicin in 5 l. 0.9% normal saline
5) Half strength povidine-iodine
6) Half strength hydrogen peroxide
7) Antibiotic irrigation (bacitracin and gentamicin in 0.9% normal saline)

* *Mulcahy JJ. Long-term experience with salvage of infected penile implants J Urol 2000 v. 163 p. 481*

Artificial Urinary Sphincter For Post-Prostatectomy Incontinence In Men Who Had Prior Radiotherapy: A Risk And Outcome Analysis

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Journal of Urology Feb 2002 v. 167(2) p. 591-596

Purpose: We retrospectively reviewed our experience with the artificial urinary sphincter for post-prostatectomy incontinence, comparing the outcome of those patients who did and did not receive previous radiation therapy.

Materials and Methods: A total of 86 patients with post-prostatectomy incontinence treated with implantation of artificial urinary sphincter includes 58 who did not (group 1) and 28 who did (group 2) receive prior radiation therapy during treatment of prostate carcinoma. In group 2 radiation was the primary treatment followed by salvage prostatectomy in 5 patients, adjuvant after radical retropubic prostatectomy 20 and after transurethral prostatic resection 3. Mean patient age plus or minus standard deviation was 68.3 ±6.6, and 69.7 ±6.6 years in groups 1 and 2, respectively. Activation of the sphincter was 4 weeks from the date of surgery, and deactivation at night was not adopted in either group. Patients were followed for a mean period of 31 ±23, and 36 ±21 months in groups 1 and 2, respectively. Comparison of continence, urodynamic testing, complication rate, overall satisfaction and quality of life was done between both groups.

Results: Reoperation was required in 13 (22.4%) patients in group 1 and 7 (25%) group 2 (p >0.05). Urethral atrophy and/or inadequate compression was seen in 8 (14%) and 4 (14%) patients, and urethral erosion was observed in 1 (2%) and 2 (7%) in groups 1 and 2, respectively (p >0.5). Infection of the device was observed in 4 (7%) patients in group 1 but none group 2 (p>0.05). Continence status was similar in both groups, with 60% and 64% of patients who wore 0 to 1 pad daily in groups 1 and 2, respectively (p >0.05). Urgency with or without urge incontinence was reported after implantation of artificial urinary sphincter in 47%, and 44% of patients in groups 1 and 2, respectively (p >0.05). On a visual analog scale (range 0 to 5, 0—not satisfied at all, 5—extremely satisfied) for satisfaction with the results of the artificial urinary sphincter 86% and 91% of patients reported 4 or greater in groups 1 and 2, respectively (p >0.05).

Conclusions: A history of radiation therapy did not affect the patient perception of success. In our work, with a visual analog scale (range 0 to 5), improvement after implantation of artificial urinary sphincter was rated 4 or greater in 88% and 96% of patients, and satisfaction with the overall results of artificial urinary sphincter 4 or greater in 86%, and 91% in groups 1 and 2, respectively (p >0.05). Of patients in groups in 1 and 2, 94% and 96% would recommend the artificial urinary sphincter to a friend, and 90% and 96% would undergo implantation again, respectively (p >0.05). Similarly, of 15 patients with post-prostatectomy incontinence and prior radiotherapy Litwiller et al found that 80% expressed great satisfaction, 87% would recommend the sphincter to a friend and 93% would, in retrospect, undergo the procedure again. In this last study, considering the whole patient group, great satisfaction, recommendation of the artificial urinary sphincter to a friend and to do it again were seen in 90%, 96% and 92% of patients, respectively, who are comparable to those who had radiation. We conclude that the artificial urinary sphincter has a similar outcome in patients with postprostatectomy incontinence, whether or not they have had previous radiation therapy. No special precaution needs to be adopted in group 2 regarding operative or postoperative care.

Table 5: Complications and reoperations

	No. Pts. (%)				p Value
	Group 1		Group 2		
Complications:*					
Urethral atrophy	8	(14)	4	(14)	1.0
Erosion	1	(2)	2	(7)	0.2
Infection	4	(7)	0.0	(0.0)	0.3
Leakage in device	2	(3)	0.0	(0.0)	1.0
Pump malfunction	0.0	(0.0)	1	(4)	0.3
Pump malposition	2	(3)	0.0	(0.0)	1.0
Superficial perineal abscess	1	(2)	0.0	(0.0)	
No. reoperations: +	13	(22.4)	7	(25)	0.8
1	8	(13.8)	5	(18)	
2	4	(8.6)	2	(7)	
3	1	(2)	0.0	(0.0)	

** Some patients had greater than 1.*
+ Pending reoperations are included.

Transcorporal Artificial Urinary Sphincter Cuff Placement In Cases Requiring Revision For Erosion And Urethral Atrophy

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Journal of Urology May 2005 v. 167(5) p. 2075-2079

Purpose: A distal cuff location is often required in patients undergoing artificial urinary sphincter reimplantation after previous erosion or in those requiring revision because of urethral atrophy at the original cuff site. Dissecting the urethra at a more distal site increases the risk of urethral injury and erosion, and often the urethral circumference is so small that a 4 cm. cuff is too large. We present a novel technique for distal cuff placement using transcorporal dissection that leaves corporal tunica albuginea on the dorsal surface of the urethra, allowing for its safer mobilization and adding to its bulk.

Materials and Methods: We reviewed the charts of 31 men who underwent this technique and contacted 26 by telephone. The indications for distal transcorporal cuff placement varied. In 7 men with inadequate urethral coaptation with a 4 cm. proximal cuff at initial implantation a primary transcorporal tandem cuff was implanted distal. In 8 men persistent or recurrent incontinence despite a 4 cm. proximal cuff led to secondary distal reimplantation. Previous artificial urinary sphincter erosion and/or infection in 10 cases, previous urethral surgery at the optimal cuff site in 5 and radiation changes at the optimal cuff site in 1 led to selection of the more distal site and technique. Of the transcorporally placed cuffs 18 were 4 cm. and 13 were 4.5 cm. Preoperatively 5.2 pads were used daily. Of the 31 patients 27 were impotent preoperatively, 1 had normal erections, 1 had partial erections with the MUSE drug delivery system (Vivus, Inc., Menlo Park, California) and 2 had a previously placed penile prosthesis.

Results: At a mean followup of 17 months 26 of the 31 patients (84%) had occasional or no stress incontinence requiring 0 to 1 pad daily, 2 with pure urge incontinence used 1 to 2 pads daily and 3 had mixed incontinence requiring 0 to 3 pads daily. Of the 26 men surveyed 25 were very satisfied with the postoperative level of incontinence. Postoperatively erectile function deteriorated in 1 patient and was unchanged in the remainder. There was no erosion or infection of the transcorporally placed cuffs, although 3 were replaced for malfunction.

Conclusions: This technique offers significant advantages in cases of revision. The technique protects the urethra from intraoperative dissection injury and decreases the risk of erosion because the urethra is buttressed at its vulnerable location. In addition, bulk is added to the urethra, allowing for better cuff sizing, which is usually a problem at this location where the urethra is small, thereby, improving continence in revised cases. Our success has recently led us to abandon tandem cuff placement altogether. There is a potential for deteriorating erectile function in potent men who undergo implantation in this fashion.

Notes

** A select number of articles were chosen based on high patient enrollment and varying surgical approaches from peer reviewed journals*

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