The Impact of Urethral Risk Factors on Transcorporeal Artificial Urinary Sphincter Erosion Rates and Device Survival

Stephen Mock,* Roger R. Dmochowski,† Elizabeth T. Brown,‡ W. Stuart Reynolds, Melissa R. Kaufman§ and Douglas F. Milam‖

From the Department of Urologic Surgery, Vanderbilt University Medical Center, Nashville, Tennessee

Abbreviations and Acronyms

AUS = artificial urinary sphincter

IPP = inflatable penile prosthesis

SHIM = Sexual Health Inventory for Men

TC = transcorporeal

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* Correspondence: Vanderbilt University Medical Center, A-1302 Medical Center North, Nashville, Tennessee 37232 (telephone: 610-283-3576; FAX: 615-322-8990; e-mail: Stephen.mock@vanderbilt.edu).

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‡ Financial interest and/or other relationship with Society of Women in Urology.

§ Financial interest and/or other relationship with Cook Myosite and AMS.

‖ Financial interest and/or other relationship with Medtronic.

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Purpose: We report the impact of urethral risk factors on erosion rates and device survival outcomes after transcorporeal artificial urinary sphincter placement.

Materials and Methods: We performed a retrospective analysis of all transcorporeal artificial urinary sphincters placed at a single institution between January 2000 and May 2014. We assessed patient demographic, comorbid diseases and surgical characteristics for risk factors considered poor for device survival. Risk factors were compared to postoperative complications requiring explantation, including cuff erosion, infection and device revision.

Results: A total of 37 transcorporeal artificial urinary sphincters were placed in 35 men. Placement was performed as a primary procedure in 21 of 37 cases (56.8%) and as salvage in the remainder. In this transcorporeal population there were 7 explantations (18.9%) due to erosion in 4 cases, cuff downsizing in 2 and infection in 1. Median followup from implantation to last followup was 8.5 months (range 0.9 to 63). Median time from artificial urinary sphincter placement to explantation was 17.3 months (range 0.9 to 63) and time specifically to transcorporeal erosion was 7.4 months (range 0.9 to 26). On univariate analysis no parameters were associated with sphincter cuff erosion but a history of an inflatable penile prosthesis was associated with a higher device explantation rate (60% vs 12.5%, $p = 0.04$). No associations were revealed on multivariate logistic analysis. All 4 cuff erosion cases demonstrated greater than 2 urethral risk factors, including prior radiation therapy in all. The probability of cuff erosion in patients with 2 or more urethral risk factors was 1.65 times the probability of erosion in those with 0 or 1 urethral risk factor (95% CI 1.3, 2.2). The proportion of patients free of erosion at 35 months was 100% in those with 0 or 1 urethral risk factor and 64% in those with 2 or more risk factors (log rank test $p = 0.00$). Similarly the proportion of patients free of explantation at 35 months was 100% in those with 0 or 1 urethral risk factor and 52% in those with 2 or more (log rank test $p = 0.02$).

Conclusions: Transcorporeal artificial urinary sphincter implantation is generally reserved for complex and high risk cases but favorable functional results were demonstrated. However, patients with multiple urethral risk factors face a higher risk of erosion and device loss.

Key Words: urethra; urinary bladder; urinary sphincter, artificial; prostheses and implants; complications

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An AUS is the gold standard treatment for moderate to severe male stress urinary incontinence with proven long-term efficacy and high patient satisfaction rates.[1,2] However, significant risks such as urethral cuff erosion or infection requiring device explantation occur in 0.46% to 9.5% of primary AUS cases.[3–8]

Importantly complication rates may be even higher in those with unfavorable risk factors, including prior radiotherapy, urethral stricture disease, previous surgical procedure(s) such as urethroplasty or prior AUS explantation.[9–12] In compromised/frail urethras AUS complications may be due to prior changes to urethral tissue, urethral blood flow disruption or urethral stricture necessitating future urethral surgery with the sphincter cuff in situ. Direct urethral injury resulting from separating an atrophic, poorly vascularized urethra from the underlying corporeal body is uncommon but can also occur. In these circumstances small series have demonstrated decreased device survival compared to primary implantation.[11,12]

Surgical modifications of the cuff implantation technique have been introduced in an attempt to reduce the risk of cuff erosion. Subsequent cuff placement is commonly done in a new, usually distal location.[13,14] Wrapping the urethra with xenograft material in an effort to protect the urethra and increase urethral circumference have been described but have not gained wide acceptance.[15] Alternatively a TC technique of AUS cuff placement is a way to avoid posterior urethral dissection, preserve some blood supply and incorporate a layer of cavernous tissue between the AUS cuff and the dorsal surface of the urethra.[13] While there is no randomized trial demonstrating that TC placement impacts cuff erosion and ultimately device survival rates compared with traditional approaches, multiple series have rates similar to or lower than previously published studies in high risk population.[10,11,14,16]

To our knowledge we report the largest single institution series of TC AUS placements to date with special emphasis on clinical and preoperative parameters that may impact cuff erosion and device survival.

METHODS

After receiving institutional review board approval we retrospectively reviewed our series of 374 consecutive AUS placements between January 2000 and May 2014. A TC approach was used in 43 cases. Excluded from analysis were 5 patients who lacked followup after placement and 1 who ultimately underwent supratrigonal cystectomy and urinary diversion for end stage urethral disease. A high volume surgeon (DFM) placed 21 of the 37 sphincters (57%). The remainder were placed by another faculty member and former fellow (MRK) using a similar surgical technique.

Table 1. *Patient demographics and preoperative clinical parameters*

	No. Pts (%)
TC reason:	
Spongiosal atrophy	16 (43.2)
Prior erosion	16 (43.2)
Severe fibrosis	5 (13.5)
Urethral cuff size (cm):	
4	6 (16)
4.5	14 (39)
5	11 (31)
5.5	5 (14)
Comorbidities:	
Diabetes	11 (29.7)
Smoking	3 (8.1)
Chronic obstructive pulmonary disorder	3 (8.1)
Androgen deprivation therapy	6 (16.2)
Urethral risk factors:	
Radiation	28 (75.7)
Prior explantation for infection/erosion	16 (43.2)
Prior IPP	5 (13.5)
Prior urethroplasty	2 (5.4)
Prior sling	3 (8.1)
Prior tandem cuff	2 (5.4)
Post implantation urinary retention	4 (10.8)
Bladder neck contracture/procedure history	19 (51.4)
UroLume® stent placement history	4 (10.8)

The operative technique of TC cuff placement was performed as previously described.[13,17] The decision for TC placement was made on an individual basis considering patient history and intraoperative findings (tables 1 and 2). In primary cases TC was chosen if spongiosal atrophy was such that it would preclude even the smallest cuff size and/or if dissection between the urethra and the corporeal bodies was deemed too hazardous due to obliterated surgical planes. Although most of this cohort was impotent at baseline, for those who were potent TC was still offered if the burden of incontinence outweighed patient concern for the potential risk of post-TC erectile dysfunction.

Corporotomies were closed selectively using 2-zero polydioxanone sutures based on subjective determination of corporeal bleeding and AUS cuff fit.[13] Drains were not used. Postoperatively the device was locked in the

Table 2. *Univariate analysis of TC AUS erosion rates by risk factors*

Risk Factors*	% Erosion	RR (95% CI)
Urethral:		
History of radiation	14.3	Not applicable
Prior explantation	18.8	3.9 (0.5, 34)
Prior IPP	40	6.4 (1.1, 35.7)
Prior urethroplasty	50	5.8 (1.0, 33.8)
Postimplantation urinary retention	25	2.75 (0.4, 20.6)
Bladder neck contracture/procedure history	15.8	2.8 (0.3, 24.9)
Systemic:		
Diabetes	18.2	2.4 (0.4, 14)
Androgen deprivation therapy	16.7	1.7 (0.2, 14)

* No erosion associated with certain urethral risk factors (prior sling, prior tandem cuff and UroLume stent placement history) or certain systemic risk factors (current smoking and chronic obstructive pulmonary disease).