Does Use of a Second Cuff Improve Artificial Urinary Sphincter Effectiveness? Evaluation Using a Comparative Cadaver Model

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Abbreviations and Acronyms

AUS = artificial urinary sphincter RLPP = retrograde leak point pressure

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Purpose: The artificial urinary sphincter is the gold standard long-term solution for male stress incontinence. Some urologists believe that including a second urethral cuff at the time of placement can improve efficacy but strong evidence is lacking. We compared the functionality of a single vs a tandem cuff in a cadaver model.

Materials and Methods: Artificial urinary sphincter reservoir pressure was confirmed at 61 to 70 cm $\rm H_2O$. The bulbar urethra was dissected through a perineal approach in each of 4 cadavers. Distal and proximal bulbar urethral circumference was measured. The membranous urethra was transected. Cuffs sized based on circumference measurements were placed distal and proximal, and connected to the reservoir and pump. Retrograde leak point pressure was measured sequentially across the distal, proximal and tandem cuffs. We used the Friedman test to compare retrograde leak point pressure among the 3 cuff positions, the paired t-test to compare distal and proximal urethral circumferences and the Spearman correlation to compare urethral circumference to retrograde leak point pressure.

Results: Mean retrograde leak point pressure across the distal, proximal and tandem cuffs was 73.5, 77.75 and 79.25 cm $\rm H_2O$, respectively (p = 0.44). Mean urethral circumference of the distal and proximal bulbar urethra was 4.78 and 5.83 cm, respectively (p = 0.019). There was a strong positive correlation between urethral circumference and retrograde leak point pressure ($\rm r_s = 0.5$).

Conclusions: The tandem cuff did not improve retrograde leak point pressure. Proximal bulbar urethral circumference was greater than distal circumference and increasing urethral circumference correlated with increasing retrograde leak point pressure. Therefore, the perceived benefit of tandem cuffs may reflect more proximal placement of one of the cuffs.

Key Words: urinary bladder; urinary sphincter, artificial; urinary incontinence; urodynamics; cadaver

Stress urinary incontinence is the unwanted loss of urine during physical activity such as lifting or coughing, which occurs due to weakening of the external urinary sphincter muscle. In men this is most commonly precipitated by injury, often through surgery, radiation or trauma. Of men

in whom stress urinary incontinence develops after prostate cancer therapy 10% pursue surgical intervention to improve continence. The gold standard surgical treatment for severe stress urinary incontinence in men is the AUS. Approximately 80% of patients who receive an AUS achieve

social continence, defined as using 1 or fewer pads per day. Urologists have tried different techniques to improve device effectiveness, including increasing balloon reservoir pressure, decreasing urethral cuff circumference, relocating the cuff along the urethra and adding a second (tandem) cuff. ^{2,3}

The tandem cuff technique is based on the concept that a longer occlusive segment of urethra would enhance the overall effectiveness of the AUS by increasing total resistance to urine flow, much like the additive effect of placing 2 electrical resistors in series.2 However, beyond a number of observational case series in the literature this technique is backed by little empirical evidence. 2,4,5 In addition there are potential risks to consider with placement of a second cuff. The longer resistive section may increase the potential for urethral erosion as the segment of urethra between the cuffs may be at increased risk for ischemia. Although it is not standard practice and evidence is lacking, the tandem cuff technique is used about 15% of the time (American Medical Systems, personal communication).

Due to this ambiguity we directly investigated tandem cuff functionality. To compare the single vs the tandem cuff AUS we measured urethral RLPP, that is the fluid pressure at which occlusion of the cuff is overcome and it leaks. Like antegrade leak point pressure, RLPP has been shown to inversely correlate with pad use. Therefore, RLPP was our surrogate measure of sphincteric continence and device effectiveness. We hypothesized that there would be no difference in RLPP of the single and the tandem cuff AUS.

MATERIALS AND METHODS

The standard AUS placement technique was performed in 4 fresh unfixed male cadavers. The pressure rating of the AUS reservoir was first confirmed to be between 61 and 70 cm $\rm H_2O$ using a burette test. The bulbar urethra was dissected via the perineal approach. Distal and proximal bulbar urethra circumferences were measured by placing a string around these locations and cutting it to the exact dimension. The distal and proximal bulbar urethra was differentiated at the crus. One AUS cuff was placed in the most proximal aspect of the bulbar urethra and a second cuff was placed more distal. The cuffs were connected to the reservoir and the pump (fig. 1).

The cuffs were sized based on the urethral circumference measurements as is done in our clinical practice. For a urethral circumference less than 4.5 cm a 4.0 cm cuff was used, for a circumference of 4.5 cm or greater a 4.5 cm cuff was used and for a circumference of 7.0 cm or greater a 5.0 cm cuff would have been used (see table). The membranous urethra was transected to allow for accurate assessment of RLPP. Across the distal, proximal and tandem cuffs RLPP was then measured sequentially. When a cuff was not being tested, it was disconnected from the system and unfastened from the urethra.



Figure 1. Measuring RLPP across tandem cuffs

RLPP was measured by inserting a 16Fr catheter in the distal urethra and connecting it to a fluid reservoir, which could be raised to alter infusion pressure. Pressure was increased until it exceeded the occlusive force of the cuff and leakage was observed at the transected urethra. The height differential between the cuff and the fluid level was recorded as RLPP. Food coloring was added to the fluid to help visualize initial leakage across the cuffs (fig. 1).

We used the Friedman test to compare RLPP among the 3 cuff positions, the paired t-test to compare distal and

RLPP and bulbar urethral circumference

	Cadaver No.				
	1	2	3	4	$\text{Mean} \pm \text{SD}$
RLPP (cm H ₂ O):*					
Distal cuff	75	79	64	76	73.5 ± 6.56
Proximal cuff	78	85	82	66	77.75 ± 8.34
Tandem cuffs	80	83	82	72	79.25 ± 4.99
Bulbar urethral circumference (cm):†					
Distal	5.2	4.9	5.0	4.0	4.78 ± 0.53
Proximal	6.8	6.0	6.0	4.5	5.83 ± 0.96

p = 0.44

tp = 0.02.

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