Adjustable Balloon Implants (ProACT®) for Post-Prostatectomy Stress Urinary Incontinence: A Single-Surgeon Experience

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INTRODUCTION

- Stress urinary incontinence affects up to 70% of men following radical prostatectomy.
- The ProACT system is an FDA-approved alternative to artificial urinary sphincter and male sling placement for mild to severe post-prostatectomy stress urinary incontinence (ppSUI)[1].
- The ProACT system involves two adjustable balloons placed transperineally under fluoroscopic guidance at the bladder neck to increase bladder outlet resistance
- Placement is performed in the outpatient setting and the balloon volume is titrated by 1mL increments until the desired continence is achieved

METHODS

- IRB approved, retrospective review of outcomes after ProACT device placement for ppSUI at our institution. (IRB20220159)
- 27 patients identified during the study period and two were excluded from continence analysis due to explanted devices.
- Patients were evaluated at post-op visit and 6-week intervals for device adjustments to a device-label maximum of 8mL per balloon.
- The Male Stress Incontinence Grading Score (MSIGS) was used as our objective metric of ppSUI, with the scores ranging from 0-4.
- MSIGS was assessed at each visit prior to consideration for incremental fill.

RESULTS

MSIGS	PROPORTION OF STUDY SAMPLE	PROPORTION WHO ACHIEVED MSIGS 0	PROPOTION WHO CLINICALLY IMPROVED	PROPORTION WHO BECAME DRY
GRADE 0 (LEAK PER HISTORY)	8% (N=2)	100% (N=2)	100% (N=2)	100% (N=2)
GRADE 1 (DELAYED DROPS)	12% (N=3)	100% (N=3)	33% (N=1)	67% (N=2)
GRADE 2 (EARLY DROPS)	16% (N=4)	25% (N=1)	50% (N=2)	50% (N=2)
GRADE 3 (DELAYED STREAM)	12% (N=3)	67% (N=2)	100% (N=3)	67% (N=2)
GRADE 4 (EARLY STREAM)	52% (N=13)	38.5% (N=5)	30.8% (N=4)	23.1% (N=3)

Table 1: Pre-op MSIGS with correlative definition. The grade is measured with a 4 cough standing test with at minimum 60 minutes since the last void for urine pooling at the bladder neck. Clinical improvement is defined as a ≥ 50% reduction in pads used per day (PPD). Dryness is defined as ≤ 1 PPD.[2,3]

- Among the 25 patients analyzed, 5 patients had either salvage radiation or salvage prostatectomy after radiation.
- Median age was 73
- The average fill volume per balloon was 4.1mL
- Median follow-up was 13.5 months.
- Across our cohort, **mean MSIGS improved 1.76 points** ($p<0.001$) upon the final fill within our study period. 13 pts reached an MSIGS score of 0. 11 pts clinically improved, and 11 pts are now dry.

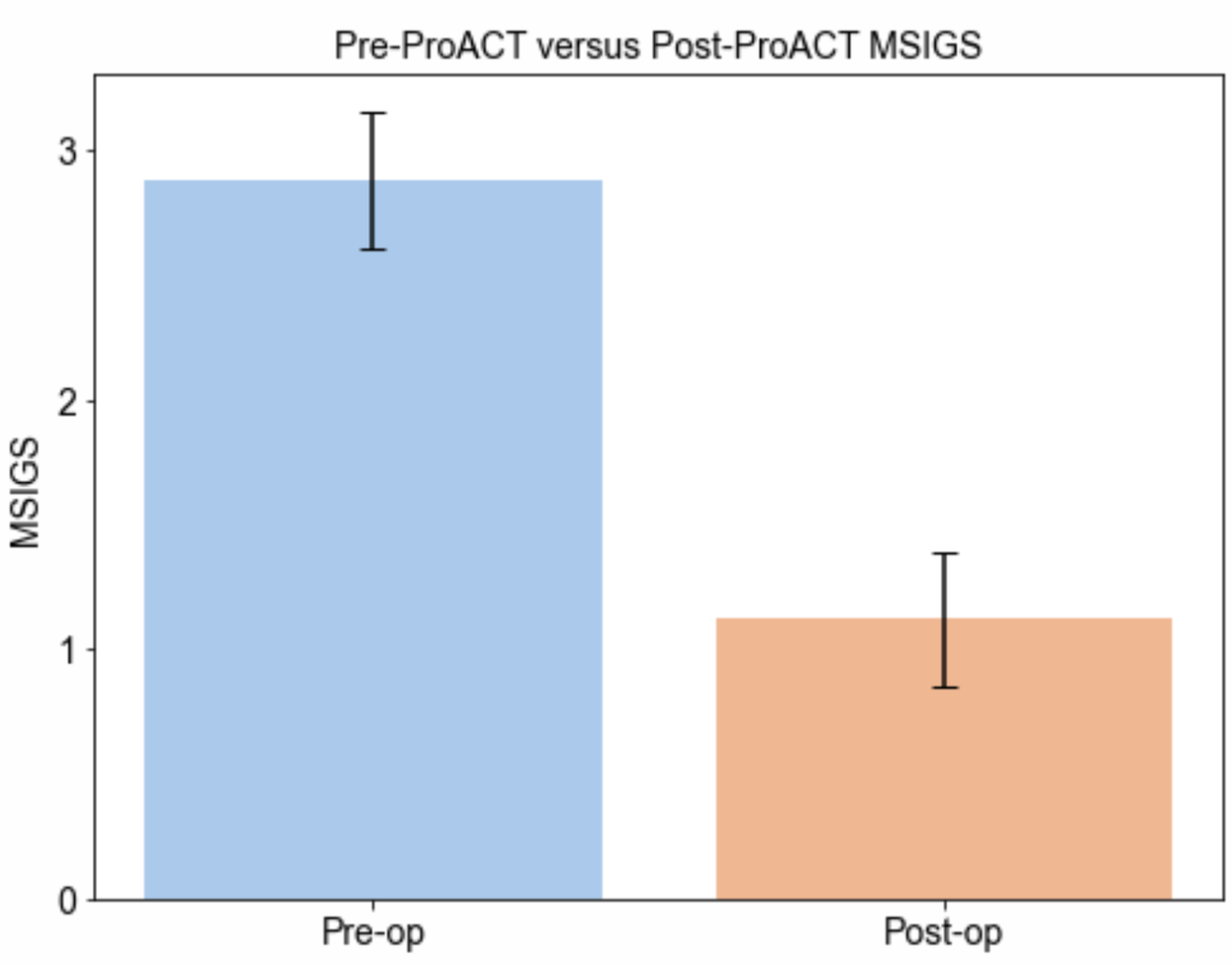

Figure 1: Mean MSIGS grades ± SEM reported. Pre-op scores represent the MSIGS measurement closest to the operative date and post-op measurements were made at the final fill visit. ($p<0.001$)

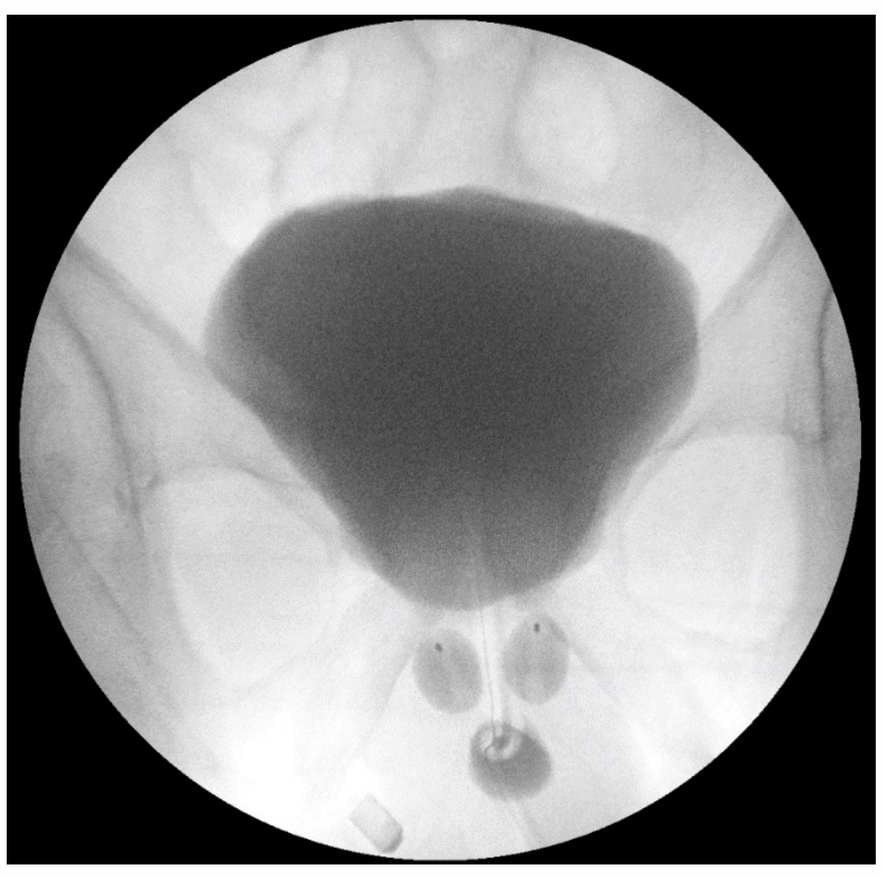

Figure 2: Representative fluoroscopic imaging of initial ProACT balloon placement. Balloons are each filled with 1mL of an isotonic mixture of contrast and saline at the time of placement. Adjustments are typically made in 1 mL intervals until satisfactory continence is achieved

CONCLUSIONS AND LIMITATIONS

- The ProACT adjustable balloon system is an effective, minimally invasive treatment option for ppSUI that results in a statistically significant improvement in MSIGS scores
- Future study should be performed to validate the use of MSIGS as a postoperative assessment tool by correlating with pad usage.
- Limitations of the MSIGS measurement exist as any physical exam maneuver. Variability can be minimized and reliability optimized by waiting the requisite 60 minutes post void, however patients with severe incontinence may not have the storage ability to perform an appropriate MSIGS evaluation

References:

1. Nash S, Aboseif S, Gilling P, et al. Treatment with an adjustable long-term implant for post-prostatectomy stress incontinence: The ProACT™ pivotal trial. Neurourol Urodyn. 2018;37(8):2854-2859. doi:10.1002/nau.23802
2. Morey A, Singla N, Chung P, et al. Male Stress Incontinence Grading Scale (MSIGS) for Evaluation of Men with Post-Prostatectomy Incontinence: A Pilot Study. Video J Prosthet Urol. 2016;2:64.
3. Larson T, Jhaveri H, Yeung LL. Adjustable continence therapy (ProACT) for the treatment of male stress urinary incontinence: A systematic review and meta-analysis. Neurourol Urodyn. 2019 Nov;38(8):2051-2059. doi: 10.1002/nau.24135. Epub 2019 Aug 20. PMID: 31429982.