

## Periurethral constrictor: late results of the treatment of post prostatectomy urinary incontinence

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### ABSTRACT

*Objectives:* We evaluated retrospectively, the long-term outcome of patients with post-prostatectomy urinary incontinence (PPUI) after placement of the Periurethral Constrictor (PUC).

*Materials and Methods:* Fifty-six men with severe PPUI were studied, with a mean age of 68.5 years old. Fifty-one men had PPUI due to radical surgery having the device placed around the bulbous urethra, and five individuals with benign prostatic hypertrophy (BPH) had placement around the bladder neck. The mean follow-up was 82.2 months.

*Results:* Twenty-two patients (39.28%) became continent (0 to 1 pad a day) and 34 (60.72%) were incontinent. Complications were as follows: urethral erosion in 15 (26.78%); mechanical malfunction in 2 (3.5%); infection in 2 (3.5%); urinary fistula in 1 (1.7%); Urinary tract infection 1 (1.7%). Twenty-three patients needed to have the device removed (41.07%). Success rate (continent me) was 30.35%.

*Conclusion:* In the present series the PUC was not effective for the treatment of severe PPUI in the long-term follow-up.

*Key words:* urinary incontinence; prostatectomy; prostate; prosthesis implantation; adverse effects

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### INTRODUCTION

Urinary incontinence is a complication of great impact on quality of life of patients undergoing radical prostatectomy (1). Its occurrence is quite variable (2), however only 5% of patients will require invasive treatment (3). Since the eighteenth century many devices and surgical procedures were described (4-8), but only the AS 800 artificial sphincter, first introduced by Scott et al. in 1973 (9), achieved satisfactory results and remains the gold standard for the treatment of urinary incontinence after prostatic surgery for over 30 years (10-12).

An original device called Periurethral Constrictor (PUC) was described by Lima et al. in 1996. It was designed for implantation around the bladder neck in the pediatric patients to strengthen

the continence mechanism in combination with bladder augmentation in patients with neurogenic bladder with low compliance and reduced urethral resistance. Satisfactory continence results were obtained up to 80% of cases. Two features are interesting with this device: its low cost and the ability to adjust the cuff pressure through percutaneous puncture, features not offered by the AS 800 (13-15). Its use was extended for patients with urinary incontinence post-prostatectomy. The aim of this study was to evaluate, retrospectively, the long-term results of the implantation of the CPU in 56 patients with post-prostatectomy urinary incontinence (PPUI).

### MATERIALS AND METHODS

From January 1995 to July 2007, 56 men with PPUI underwent implantation of the PUC. All patients had preoperative evaluation that included

history, especially regarding the use of pads, physical examination, urine culture, total PSA, urodynamic evaluation, primarily to assess the presence of detrusor overactivity and Valsalva leak point pressure and cystourethrography, to exclude urethral stricture or bladder neck anastomosis stenosis. No patient had evidence of recurrence of prostate cancer.

The PUC is a 1-piece device of medical silicone that has an adjustable cuff with capacity of 6cc connected by a 20 cm tube to a port in the other extremity. The adjustable cuff is inserted around the bladder neck or bulbous urethra and the pins were connected according to the external urethral diameter. There are 3 sets of pins.

Patients who had post radical prostatectomy urinary incontinence had the device implanted around the bulbous urethra using a perineal incision. The puncturing port was implanted subcutaneously at the iliac fossa. Patients with urinary incontinence after adenomectomy (BPH) had the PUC implanted around

were implanted the Peri-urethral Constrictor around the bulbous urethra while in five men (8.93%), around the bladder neck. These 5 patients had PPUI post transvesical simple prostatectomy due to BPH and the first group was submitted to radical prostatectomy.

Of the 56 patients, 23 (41.07%) required device removal for complications listed below, and 33 (58.93%) remained with the device in situ. The average time between surgery and removal of the device, was 22.6 months (3.73-88.6). Of the five patients with bladder neck placement, only one patient had the device removed, three were continent, one patient experienced temporary continence after becoming incontinent.

The complications were: erosion of the urethra in 15 patients (26.78%), mechanical malfunction in 5 (8.9%), urethral stenosis in 3 (5.3%), urinary fistula in 2 (3.5%), infection in 2 (3.5%) and 1 case of urinary tract infection (1.7%). Two deaths occurred from causes unrelated to the device (Table-2). Be-

**Table 1 - Age and clinical follow-up of 56 patients of 56 patients of 56 patients of 56 patients .**

	Mean	Average	SD
Age	68.57	46-86	5.85
Follow-up time in months	82.26	3-174	44.91

the bladder neck through an abdominal route, with the port in the same location as for the perineal approach.

The variables studied were age, length of follow-up, anatomic site of implantation of the device, causes of removal of the device, type of the complication and continence (0-1 pad/day). Success was considered when patients became continent (0-1 pad/day) with the device placement and failure when the patients were incontinent with removal or not of the device.

**RESULTS**

The average age of patients submitted to intervention was 68.5 years (ranging from 46 to 86), all male. The mean follow-up was 82.2 months (range 3 to 174) (Table-1). In 51 (91.07%) patients (out of 56

tween 1995 to 2000, from a total of 22 patients 8 men (36 %) had removal of device. From 2001 to 2007, 15 of 34 patients (44%).

Twenty-two patients (22/56) were continent (39.3%) and 34 (34/56) remained incontinent (60.7%). In patients in whom the device was not removed (33 patients), 17 were continent (51.2%) and 18 were incontinent (48.8%) (Table-3).

A total of 17 (30.35%) patients had successful urinary continence due to the device placement. The remaining 39 patients (69.65%) were considered failure.

**DISCUSSION**

There are at least 2 distinct 2 schools of thought regarding treatment of PPUI. One group believes

**Table 2 - Complications requiring removal of PUC.**

	Removal		No removal		Total	
	n	%	n	%	n	%
Complications	23	41.07	33	58.93	56	100%
Urethral erosion	15	26.8	0	0		
Urinary fistula	1		1	1.7		
Urinary tract infection	0	0	1	1.7		
Urethral stenosis	1	1.7	2	3.5		
Mechanical malfunction	2	3.5	3	5.3		
Infection	2	3.5	0	0		

that fixed compression with increased urethral resistance may yield a physiologic micturition when intra-abdominal and bladder pressures are raised. Usually, these devices tend to have simpler mechanisms, are low cost and easier to place them surgically. This group has the disadvantage of fixed pressure over the tissues, especially the urethra and limited efficacy in patients with severe incontinence. The other school of thought believe in dynamic compression, which brings good outcomes, especially in severe urinary incontinent men. These devices are more sophisticated with higher complexity of its mechanism. High rates of revision, the need of patient's activation intervention, high cost and more complex surgical technique are the main features of dynamic compression (16). This study evaluated the retrospective analysis of PUC use in 56 patients with severe IUPP. Initially, this device was designed and used to pediatric treatment of urinary incontinence with placement of the device around the bladder neck (13). The basic idea when proposing this device was to strengthen the continence zone with the possibility of reducing or increasing the resistance

at the sphincteric area through percutaneous puncture, feature not found with other sphincter models (AS 800). This feature was later incorporated into other devices such as the devices proposed by Inci et al. (17) in 2008 and ProACT (18-20).

Except for the papers published by the PUC inventors using mostly in pediatric population, few studies have been published with the use of this device in PPUI. Two groups have published limited experiences with the use of this device in the present indication (21,22).

Simone et al. (21) evaluated 43 patients with PPUI surgically treated with PUC. The success rate was 86%, opposed to that obtained in our study. The criticism to this study is that it does not report follow up time, whereas our study has mean of 82.3 months and, most importantly, it excluded patients with severe incontinence, which were present in 100% of our patients. Rezende Junior et al. (22) reported a high success rate (75%) with severe PPUI. They had 18.75% removal rate of the device mainly due to erosion and infection of the device. Complications were also presented in the series, however with a higher percentage.

**Table 3 - Continence and incontinence rates in patients that had the Artificial urinary sphincter in situ or removed.**

	Removal	No removal	Total
Continence	5	17	22 (39.3%)
Incontinence	18	16	34 (60.7%)
<b>Total</b>	<b>23</b>	<b>33</b>	<b>56</b>

Despite the PUC belongs to the same category of devices (fixed adjustable compression) studies with ProACT (18-20) and the device proposed by Inci et al. (17) that reported a success rate above 80% were discordant from our findings (25%). Only Simone et al. (21) and Rezende Junior et al. (22) had comparable rates using the PUC. Our success rate (30%) is only comparable to long term success rates of injectable therapy (20%) (23,24) with higher morbidity.

The present study showed a very high device removal rate (41.07%). Urethral erosion was the main complication for this event. There was no relationship with the learning curve, because the contemporary series indicate even greater removal rate in the last 7 years compared to the first six years of the series (44% x 36%). This complication is also described for the AS 800, probably due to the circumferential high pressure urethral compression. Singh and Thomas (25) found a high rate of revision with placement of the AS 800 around the bulbous urethra (57%) compared with the membranous urethra (14%) placement or 30% using rate of revision using adjustable (20) devices. The most frequent complication found was urethral erosion in 15 patients (26.78%). Fourteen of these patients had placement around the bulbous urethra (95.4%). When comparing with the erosion rates of AS 800, ranging from 1.7% to 4.5% (26,27), the present study had higher rates of erosion. One study showed that when there is need for cuff change, AS 800's erosion rates are much higher and the surgeries are technically more difficult, ranging from 43% to 50% (28). Currently, fixed compression and adjustable devices are indicated for patients with mild to moderate incontinence (26,29). For patients with severe incontinence the standard treatment seems to be the AS 800 (27,30). The PUC in this study was used for patients with PUI classified as severe, an important variable when analysing such low success rate.

## CONCLUSIONS

The PUC was not effective in the treatment of post-prostatectomy urinary incontinence bringing complication rates higher than expected in such procedures.

## CONFLICT OF INTEREST

None declared.

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