

## ADJUSTABLE URETHRAL CONSTRICTOR FOR MALE STRESS URINARY INCONTINENCE

### **Introduction**

Urinary incontinence is a troublesome complication in men following radical prostatectomy. The artificial urinary sphincter (AUS) remains the gold standard for severe post-prostatectomy incontinence (PPI). However, both high costs and surgical revision rate don't allow to use this device as first choice treatment in every clinical setting. In the last year we have introduced the Silimed<sup>®</sup> urethral constrictor for the treatment of mild and severe stress incontinence after surgery alone or surgery and adjuvant radiation therapy. Aim of our study is to assess the feasibility and efficacy of the surgical technique that requires the placement of the device around the bulbar portion of the urethra (ventral part of the ring) and through the crura (dorsal part of the ring) to minimize the long term probability of urethral erosion.

### **Design**

26 male patients (mean age 68 years; range 62-78) with urodynamically proven PPI secondary to radical prostatectomy were recruited and gave informed consent to be enrolled in this clinical investigation. Preoperative work-up included cystography, cystometrogram, uroflowmetry and urethral pressure profilometry. 20/26 (79%) underwent surgery and adjuvant radiation therapy. 8/26 patients (30%) were sexually active. The perineal approach to the bulbar urethra was quite similar to that used to implant a AUS. However, in this surgical technique the urethral cuff was placed using a dorsal passage through the crura and cavernous bodies to lie on a good part of resistant tissue between urethra and the device. Finally we connected the cuff with the port for the adjustable refilling after surgery. This procedure was carried out without significant intraoperative complications.

### **Results**

All patients treated with the Silimed<sup>®</sup> urethral constrictor device recovered well from surgery. 2 devices were removed within the first month (1 for untreatable pain and 1 for early urethral fistula in an irradiated pelvis). No surgical complications as bleeding, infections or worsening of sexual function were observed. Urethral catheter was removed 24-36 hours after the procedure.

### **Conclusions**

This study shows the technical feasibility of the trans corporal approach for the placement of urethral constrictors to treat male urinary incontinence after prostatic surgery. The Silimed<sup>®</sup> urethral constrictor device can be considered as a cost effective and safe alternative to the placement of an artificial urinary sphincter.

<b><i>Specify source of funding or grant</i></b>	<b>NOT external funding or grant</b>
<b><i>Is this a clinical trial?</i></b>	<b>No</b>
<b><i>What were the subjects in the study?</i></b>	<b>HUMAN</b>
<b><i>Was this study approved by an ethics committee?</i></b>	<b>No</b>
<b><i>This study did not require ethics committee approval because</i></b>	<b>Surgical procedure already performed in other institutions</b>
<b><i>Was the Declaration of Helsinki followed?</i></b>	<b>Yes</b>
<b><i>Was informed consent obtained from the patients?</i></b>	<b>Yes</b>