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## **AN INTERNATIONAL MULTICENTER STUDY OF THE TREATMENT OF FEMALE RECURRENT STRESS URINARY INCONTINENCE USING THE MINIMALLY INVASIVE ADJUSTABLE CONTINENCE THERAPY (ACT)**

### **Aims of Study**

All surgical procedures used in stress urinary incontinence (SUI) have in common that secondary improvement of the operative results by adjustment is not feasible. We are reporting on using a new device (ACT) for the treatment of recurrent SUI. Study objectives were to evaluate the technical feasibility of the device implantation, to assess the effectiveness and to quantify risks of adverse effects.

### **Methods**

ACT (Uromedica Inc., Plymouth, MN, USA) consists of two silicone balloons that are positioned periurethraly at the bladder neck. Each balloon is attached to a subcutaneous port situated between the major and minor labia, allowing post operative adjustments by inflating or deflating the balloons in an outpatient setting. We included 49 patients with at least one prior surgical SUI treatment. These procedures included bulking agents, slingplasty, colposuspension or artificial urinary sphincter. Clinical effectiveness was assessed by direct visual stress test and the standardized quality of life questionnaire for incontinence, I-QOL. Urodynamic measurement, I-QOL questionnaire and Direct Visual Stress Testing (DVST) were repeated at 6, and 12 and 24 month intervals.

### **Results**

Mean age of the patients was  $59.5 \pm 11.2$  years. I-QOL scores improved from  $30 \pm 18$  at baseline to  $70 \pm 23$  at 6 months ( $p < 0.0001$ ), sustained at  $72 \pm 24$  at 12 months ( $p < 0.0001$ ), and remained at  $79 \pm 13$  at 24 months ( $p < 0.003$ ). DVST demonstrated a reduction in leakage to either dry or mild leakage in 20/24 (83%) at 6 months ( $p < 0.001$ ), 14/16 (87%) at 12 months and 5/5 (100%) at 24 months post-implantation. The number of adjustments required in this group was 0.6 adjustments with an average final volume of  $3.2 \pm 2.5$  ml.

### **Conclusions**

ACT provides a unique surgical approach to SUI due to adjustability. Effectiveness of ACT could be demonstrated in these difficult patients with recurrent SUI. Especially in patients with previous incontinence surgery the ACT procedure as a minimal invasive technique provides an effective surgical approach.