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LONG TERM RESULTS OF THE ADJUSTABLE CONTINENCE THERAPY (ACT®) FOR RECURRENT FEMALE STRESS URINARY INCONTINENCE.

Hypothesis / aims of study

The Adjustable Continence Therapy (ACT®) is a minimally invasive treatment for females with Stress Urinary Incontinence resulting from Intrinsic Sphincter Deficiency (ISD). This study represents the term results of our first series of patients.

Study design, materials and methods

The ACT® device consists of two silicone balloons sited on either side of the proximal urethra under the bladder neck, each attached to a titanium port buried in the labia allowing post operative titration of the balloons. Female patients who had failed previous pelvic surgery underwent Urodynamic assessment; daily pad usage and Incontinence Quality of Life (I-QoL) questionnaire measures prior to implantation of ACT balloons and evaluated post operatively at 1, 3, 6 and 12 months then annually thereafter. Patients were also asked to record their overall impression and percentage of improvement post operatively based on the Patient Global Impression Index (PGI) and Visual Analogue Score (VAS). In addition, complications were recorded.

Results

Fifty seven females (mean age 67.2 years) have undergone ACT implantation. Mean follow up is 55 months (range 12- 72 months). At last follow-up, mean pad usage improved from 5.6 at baseline to 0.41 and IQOL improved from 27.2 -78.6 with 68% patients completely dry based on VAS. Global assessment indicated 85% were significantly improved, 17 were moderately improved and 18% remained unchanged. Postoperative complications necessitating device removal included migration seen in 7% patients and urethral erosion in 3.5% patients. Additionally, 4% balloons were explanted due to device failure. In total, 12 balloons were removed in 10 patients with only 3 patients requiring bilateral removal.

Concluding message

The relative ease of insertion and the ability to tailor this therapy to an individual patient's needs makes this a very attractive option for the challenging treatment of recurrent stress urinary incontinence due to ISD.

Specify source of funding or grant	**Collaboration with Uromedica, Medtroni, Bard, Coloplast.**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Ethical Commitee of Novara**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**