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36 MONTH FOLLOW-UP WITH ADJUSTABLE CONTINENCE THERAPY (ACT) IN FEMALE STRESS INCONTINENCE DUE TO INTRINSIC SPHINCTER DEFICIENCY (ISD)

Hypothesis / aims of study

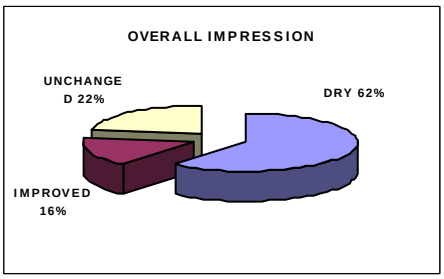
We have been implanting a new minimally invasive periurethral prosthesis for stress urinary incontinence since Dec/1999 in a multicenter study. The Adjustable Continence Therapy (ACT) implant is designed for easy post-operative adjustment via percutaneous needle access. We present an experience with a mean 3 years follow-up. While the longest follow-up is 4 years.

Study design, materials and methods

1. ACT's, made from silicone elastomer consists of two balloons placed via small labial incisions at the bladder neck. Each balloon is attached via a short length of tubing to an injectible port that is implanted in the fat of the labia, allowing for future balloon fluid volume adjustment, as required.
2. 67 female patients with type III stress urinary incontinence (SUI), with various degree of ISD, were evaluated using direct visual stress test, the Incontinence Quality of Life (I-QoL) questionnaire and abdominal leak point pressure (ALPP) evaluation prior to implantation with the ACT prosthesis. This was repeated at 1, 3, 6, 12, 24, 36 and 42 months post-op.

Results

1. Follow up: 55/67 (82%) of the patients have reached 36 months, or greater follow-up.
2. Overall impression : 41/67 (62%) patients are completely dry, 11/67 (16%) are significantly improved, while 15/67 (22%) have had insignificant or no improvement (Fig 1).
3. The ALPP increased from a mean baseline value of 60.6 +/- 38.4 cm H2O (range 1-150) to 86.2 +/- 45.1 cm H2O (range 5-180), as the last observed follow-up (p-value: 0.0032).
4. The IQOL score increased from 35.2 +/- 20.7 at the baseline to 69.9 +/- 24.6 at 36 months (p< 0.00011) (Fig2)
5. Complications reported were: bladder perforation (intra-operative) 8%, pelvic pain 4%, Urgency 1%, port erosion 10%, balloon dislocation or migration 13%, UTI in 15% All complications were easily managed without serious sequel for the patients. In the worse case this device can be easily removed in a few minutes via a local anaesthetic, thus reversing the procedure.



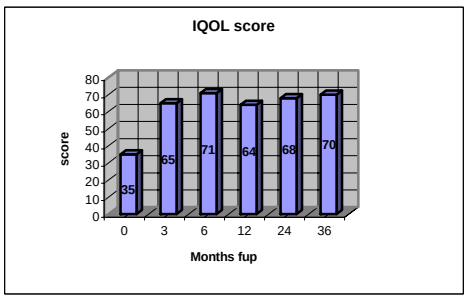


Fig 1 Fig 2

Interpretation of results

1.The ACT's adjustability, allowing the addition or removal of the balloon's volume, is a kind of fine-tuning that allows us to maintain continence despite any changes in tissue and the pelvic anatomy due to aging without resorting to another surgery.
2.The analysis of the IQOL graphs demonstrate that once the patient is showing a response by 3 m. post op. we can expect that this result will be maintained in the long term.

Concluding message

ACT is a new surgical therapy for stress incontinence that seems to show good efficacy at long term follow up.