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EUROPEAN PROSPECTIVE MULTI-CENTRE EXPERIENCE WITH ADJUSTABLE CONTINENCE THERAPY (ACT) PERIURETHRAL PROSTHESTIC IMPLANTATION: RESULTS AT 12 TO 24 MONTHS.

Hypothesis / aims of study

An entirely new concept in the treatment of female stress urinary incontinence (SUI) known as Adjustable Continence Therapy (ACT) has been used since 1999 in a multi-center European study. The aim of this study was to evaluate the safety, efficacy and durability of this implant.

Study design, materials and methods

The system consists of an adjustable silicone balloon holding up to 8 cc of isotonic solution (contrast medium and sterile water), a subcutaneous implanted titanium port with a two-lumen extrusion in between.

Using a combination of vaginal/bladder neck palpation and visual guidance under an image intensifier, the ACT balloons are placed in a postero-lateral position at the level of the bladder neck, under the endo-pelvic fascia and superior to the deeper aspect of the urogenital diaphragm (approximately at the level of the deep transverse perineal muscle and up to the level of the lateral urethral ligaments)

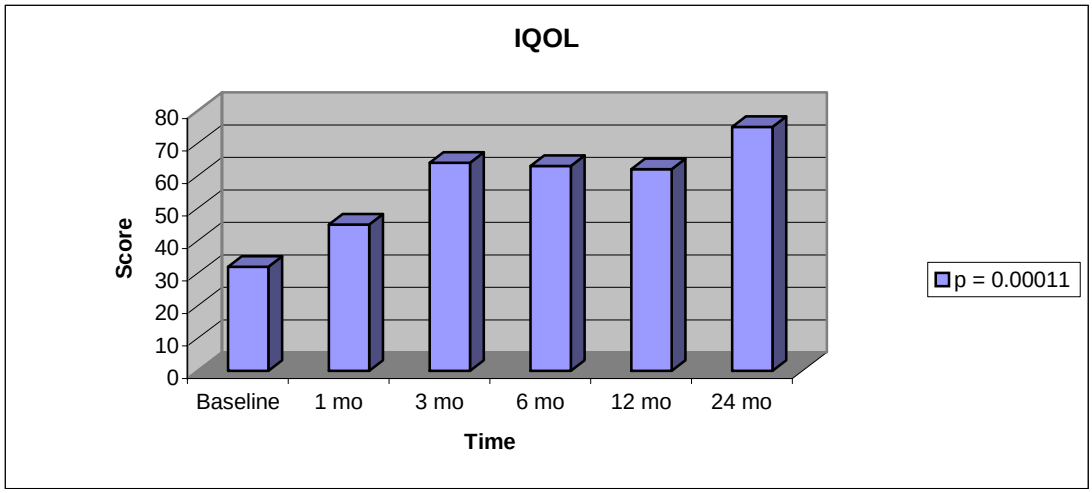
The subcutaneous port, implanted under the fatty tissue of the labia majora, communicates with the balloon for post-operative adjustments. The volume in the balloon may be adjusted via this titanium port using a 23 G needle through the skin. Adjustment can be undertaken in an office setting as early as 4-6 weeks following implantation, which allows sufficient time for the encapsulation of the device and for any oedema to resolve.

Evaluation of the first 170 patients implanted:

Since 1999, 170 patients have undergone ACT implantation in a multicenter European study. The mean age was 61.4 +/- 12.2 years (range 21.9 - 94.0). In 44% of the patients the incontinence was classified as Type II SUI while 56% patients had Type III SUI. The mean follow-up is currently 13.9 months (range 1 – 24 months), with 113 patients having reached 12 months, and 58 at 24 months follow-up. The median follow up is 12 months. The patients were evaluated using abdominal leak point pressure (ALPP) measurements and a quality of life questionnaire (IQOL) at baseline and at 3, 6, 12 and 24 months. 60 (30%) patients had prior multiple SUI surgeries: 28 (47%) had a colposuspension, 25 (42%) a slingplasty, 11 (18%) treated with bulking agents and 7 (12%) with an artificial urinary sphincter.

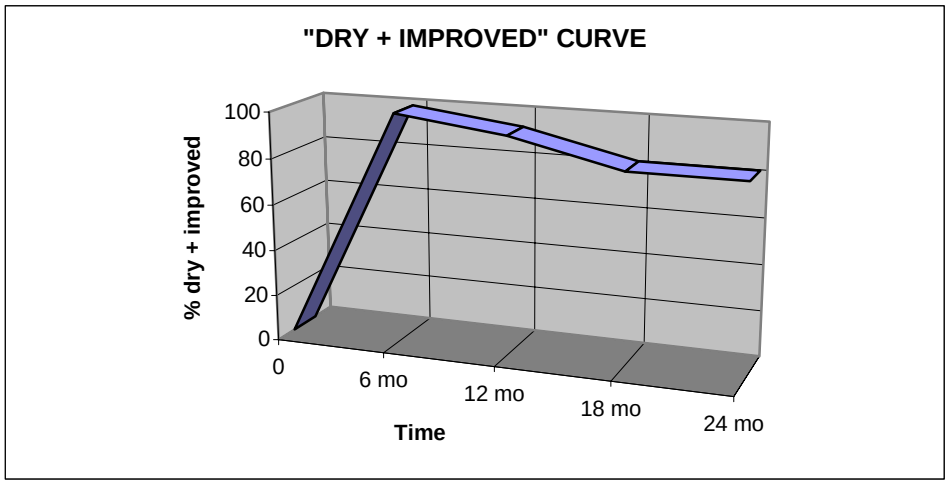
Results

An increase of the ALPP from the baseline 60.6 cm H2O +/- 38.4 (1.0, 150.0) to 86.2 cm H2O +/- 45.1 (5.0, 180.0) at the last follow up was observed (p-value: 0.0032). The baseline IQOL score increased from 35.2 +/- 20.7 to 69.9 +/- 24.6 at 12 months ($p< 0.00011$). 48/58 (82%) of patients that have reached 2 years of follow-up were either dry (= no pads) or significantly improved (= 1-2 pads/daily, satisfied and requesting no further adjustment) as shown in the dry + improved curve. The complications reported were: bladder perforation 8%, pelvic pain 4%, urgency 1%, port erosion 10%, balloon dislocation 13%, UTI in 15% and sexual discomfort (2%) of patients. In general all of these adverse events are common with other urogenital implantable devices and are easily manageable. If necessary, this device can be easily removed, thereby reversing the procedure, allowing further, more invasive intervention, if warranted.



Interpretation of results

The ACT is a bulking procedure where the bulking agent is maintained in a silicone elastomer wall that prevents the dispersion or absorption of the bulking agent. The ACT affects the restoration of continence by combining a bulking therapy with the provision of additional support of the proximal urethra and the bladder neck. The other unique property of this device is the ability for the physician to individually titrate the fluid volumes within the system via the two injectible, subcutaneously placed ports. This ability to adjust and 'fine tune' the degree of urethral co-aptation according to an individual's needs allows us to maintain continence despite any age-related changes in the tissue compliance and the pelvic anatomy, without resorting to another surgery. Analysis of the IQOL graphs demonstrate that once the patient is showing a response by 3 months after the initial implantation we can expect that this result will be maintained in the long term. Such maintenance of effect is partly the result of our ability to re-adjust the device volumes as required, from time to time.



Concluding message

The ACT represents an advance in the concept of bulking the urethra for Type III SUI and for recurrent SUI. This device has addressed many of the shortcomings of previously used 'free-fluid' based bulking substances, particularly in terms of avoiding loss of effect through unintended surgical hydro-dissection or subsequent bio-absorption of materials, individual titration the fluid volumes within the balloons so as to maximize the urethral co-aptation effect while minimizing any potential deleterious detrusor effects, and by allowing the procedure to be reversed, if required.