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Adjustable Continence Therapy for Stress Urinary Incontinence

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Many operations are used to treat women with stress urinary incontinence and outcomes are typically good. For some patients, the operation does not do enough to completely correct the problem and, for others, it can do too much resulting in new problems of voiding difficulty or incomplete bladder emptying. No operation currently done in the U.S. has offered the advantage of being adjustable. The Adjustable Continence Therapy (ACT)

System is a novel and simple, minimally invasive implantable device that helps to hold the urethra closed to improve symptoms of urinary incontinence. It has the unique advantage of being easily adjustable in the doctor's office.

The ACT device consists of two small fluid-filled balloons that are placed by the surgeon under X-ray guidance in the tissues, one on each side, just beyond the bladder neck. The balloons are inflated with .5 ml of a diluted solution of a contrasting color to tissue at the time of surgery. Each implanted balloon has tubing and an access port placed within the labial skin fold. Balloon adjustments are started at six weeks. If there is still some leakage, fluid can be added to the device or if voiding is difficult or incomplete, fluid can be removed from the device to make the outcome better.

A large multi-center study has evaluated 62 women who had failed prior treatments for stress incontinence. All patients had testing including urodynamics, cystoscopy, pad weight tests and validated questionnaires. The mean age of implanted patients was 68 years (range 3-94 years). Results at one year after treatment confirmed a significant decrease in symptoms as measured by reduced leakage on pad weight testing in 84% (94/4) of patients. Implanted patients experienced an improvement in quality of life as measured by three independent validated scores at one year. The mean number of balloon volume adjustments was two and the majority of adjustments occurred in the outpatient setting within six months of implantation.

Problems did occur in some patients and 29 had the device removed. The most frequently observed adverse events were migration, or movement, of the balloon away from the bladder neck and ulceration of the skin where the device was implanted. Device infection and urinary retention were uncommon. Thirteen patients who had problems were re-implanted and continued in the study. Most complications (73%) were considered to be mild and problems occurred more often in patients who were sexually active after surgery. It is recommended that patients avoid sexual intercourse for approximately 4 weeks following surgery.

The short-term results of treatment with this investigational device suggest that it may be an option for the treatment of recurrent stress incontinence in females. A major advantage of this device is the option to adjust the volume used to inflate the balloons to achieve continence with changes that may occur over time. To date, there have been no safety issues with the use or placement of this device. Additional follow-up is necessary to determine the long-term durability and safety of this device. ❖

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