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BENEFITS OF A POST OPERATIVELY ADJUSTABLE CONTINENCE DEVICE FOR URINARY INCONTINENCE

Aims of Study

There are a myriad of surgical procedures to treat male and female stress urinary incontinence (SUI). The decision of which intervention is most appropriate can be difficult due to the potential for over treatment, mid to long term tissue deterioration affecting efficacy and the complexity of reversal or retreatment, should this become necessary. The need to develop a technique that is both adjustable and reversible, with minimal tissue disruption becomes paramount.

Methods

Adjustable Continence Therapy (ACT™ and ProACT™) has been developed to address these clinical issues as a treatment for SUI. The system comprises of two adjustable balloons delivered via small labial or perineal incisions and positioned at the bladder neck in females and post radical prostatectomy males, and at the apex of the prostate in post benign prostatectomy patients. The balloons are attached to two titanium ports positioned sub dermally in the female labia or in the male scrotum. Initially 161 female and 64 male patients were enrolled in two separate protocols. Objective and subjective outcomes were evaluated as outpatients at baseline and at 1, 3, 6, 12 and 24 month follow up intervals. Balloon adjustments using isotonic solutions were made when necessary in the outpatient clinic or office. Results are reported on combined data.

Results

At baseline a total of 64 male patients and 161 female patients were assessed. Mean age of males enrolled was 66 years and 60 years for females. Operative time ranged from 17- 120 minutes. The initial average balloon volume at implant for male patients was 2.2 ml and for female patients was 2.1ml. Balloon volumes were not changed for the first 4 - 6 weeks post operatively to allow for pseudo capsule formation to develop and for edema resolution to occur with subsequent adjustments made every 2 - 4 weeks there after if needed. Average final balloon volume was 3.8 ml for males and 2.9 ml for females. The mean number of adjustments between baseline and last visit was 2.3 for males and 0.6 for females. In both males and females balloon volume adjustments on average were symmetrical and between 0.5 ml and 2.0 ml per balloon.

Patient response is reflected in the Incontinence Quality of Life (I-QOL) table in accordance with the frequency and volume adjustments that occurred over 24 months. The change in I-QOL score for male and female patients significantly increased ($p < 0.005$) from baseline to 24 months for both female and male for all time points except for the 24 month for male ($n=3$, $p < 0.07$).

	Baseline	1 month	3 months	6 months	12 months	24 months
No. of patients Male / Female	58/139	35/112	29/99	22/89	14/62	3/19
I-QOL Score (max. 100 points) Male / Female	41/36	51/61	59/68	71/64	68/71	72/75
P value Male and Female	-	$P < 0.001$	$P < 0.0006$	$P < 0.0002$	$P < 0.007$	$P < 0.07$, male $P < 0.0001$, female

Conclusions

The number and ease of adjustments suggest that there is clinical merit in the utilization of a post operatively adjustable device for the treatment of SUI. The ability for this therapy to be tailored to an individual patient's anatomy and needs makes this a very attractive SUI treatment option. The ACT device also offers advantages in its minimal approach and rapid recovery.