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Gallistl H[1], Huber E[1], Hubner W[1]
1. *Dept. of Urology Clinic Korneuburg*

ARGUS® AN ADJUSTABLE SLING FOR THE TREATMENT OF POST PROSTATECTOMY INCONTINENCE, 84 PATIENTS, 45 MONTHS FOLLOW UP, AN UNICENTER STUDY

Hypothesis / aims of study

Stress urinary incontinence after prostate surgery occurs in 3-60% of patients. 15-30% of the corrective operations performed after slings or hydraulic sphincter systems in such patients are considered “adjustment operations” (second slings, re-tightening, smaller cuffs, stronger reservoire – balloons etc.). Therefore adjustable systems appear to be preferable, which allow for easy adjustment secondary to possibly changing demands and conditions of the patients even years after implantation.

Study design, materials and methods

We implanted the Argus® Sling in 84 patients with an average age of 70.3 years (51-84) between 05/05 and 01/09 (45 months). 85% of these patients were previously treated with Irradiation, bladder neck incision, Macroplastique®, Invance®, Pro ACT®, AMS 800®, thus representing a “negativeselection”.
Implantation: in lithotomy position and after a longitudinal incision at the perineum, the urethra and the crura of the corpora are dissected. consequently a transverse suprapubic incision is carried out and the fascia of the rectus abdominis muscle is freed. The Argus needle is inserted between urethra and corpora cavernosa and guided retropubically towards the suprapubic field . Cystoscopy is performed to exclude bladder perforation. Retrograde leak point pressure (RLPP) is measured using the cysto sheath positioned in the penile urethra. The silicone columns are secured above the rectus fascia with the so called silicone “washers” accomplishing the desired urethral pressure (usually 30-45 cm H2O) . Wounds are closed and a 14fr foley is left in place for 48hrs.All patients were evaluated by quarterly followup visits 20 min pad test and I-QoL assessment, adjustments and complications were recorded.

Results

Mean follow-up was 24 months. Surgeries took Ø 50 min. (25–105 min) including teaching and workshops. The RLPP was adjusted to 38 (22–47) cm H2O intraoperatively. 4 intraoperative bladder perforations with the Argus needle (4.7%) healed with no complications, leaving the foley catheter for fivedays.

Interpretation of results

Pad test showed a decrease from a preoperative mean of 32g (4-117 g) to a postoperative mean of 0.87 g (0-10g). The I-QoL assessment showed an increase in the initial mean from 30.1 (7.2 - 52.2) to 63.2 mean (16.4-78.2) after implantation. Adjustment was needed in 33 cases (39%) at an average of 118 days (1-1240 days) post operatively (9 patients: loosening in general anaesthesia, 24 patients: tightening in local anaesthesia).
13 patients (15%) experienced postoperative urethral erosion after an average of 397 days (21-1260 days), reason why the sling had to be removed. A mild perineal inflammation healed conservatively. 85% of pts. are completely dry (0-1 pad).

Concluding message

Despite our negative selection of patients with 85% beeing treated otherwise before Argus® implantation the results are very satisfying. We believe that the Argus® male sling system is an excellent first or second line treatment for moderate to severe male SUI, even where prior irradiation has been undertaken, when less invasive systems are not indicated

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Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require eithics committee approval because	**yes**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**