

**ARGUS®. A NEW ADJUSTABLE SLING IN THE LOW INVASIVE TREATMENT OF POST PROSTATECTOMY INCONTINENCE**Hypothesis / aims of study

Stress urinary incontinence after prostate surgery occurs in 3-60% of patients. Due to anatomical and functional conditions and their modifications after treatment of the post prostatectomy incontinence adjustable systems have to be preferred from the therapeutic point of view (15-30% of the corrective operations usually performed in sphincter systems are considered "adjustment operations").

Study design, materials and methods

We implanted the Argus® Sling in 66 patients with an average age of 68.6 years (51-84 years) between 05/05 and 01/08 (28 months). 84.8% of these patients were previously treated with Irradiation, bladder neck incision, Macroplastique®, Invance®, Pro ACT®, AMS 800®, thus representing a "negative selection". In lithotomy position and after a longitudinal incision at the perineum, the urethra and both sides of the corpora cavernosa as well as the descending pubic rami are dissected. Finally, at the suprapubic area, after a transversal incision, the fascia of the rectus abdominis muscle appears. Then, we perforate the pelvic floor with the Argus needle between urethra and corpora cavernosa to take it out in the typical direction towards the suprapubic area. We make a cystoscopy to exclude any bladder perforation. A measurement of the retrograde leak point pressure (RLPP) is made once the bladder is filled with 200 ml. The silicone columns are threaded above the rectus abdominis muscle fascia and the silicon pad is positioned with an average 49 cm H(2)O RLPP (22–47 cm H(2)O) around the urethra. Silicone columns are attached to the rectus abdominis muscle fascia with the "washers". Patients received a 14 fr foley catheter for 24 hs; in the case of bladder perforation for 3 days. The surgery lasted Ø 50 min. (25–105 min.). The assessment was made through pad test, I-QoL questionnaires and clinical controls.

Results

Mean follow-ups were 16 months. The pad test showed a decrease in stress urinary incontinence from a preoperative mean of 36g (4-117 g) to a postoperative mean of 0.77 g (0-10g). The I-QoL assessment showed an increase in the initial mean from 28,8 (7.2 - 52.2) to 60.6 mean (16.4 - 78.2) A later adjustment was made in 22 cases (33.3%) in an average of 60 days (1-240 days). 9 patients: loosening in general anesthesia, 13 patients: tightening in local anesthesia. 4 bladder intra-operative perforation (6%) healed with no complications, leaving the foley catheter for 5 days . A slight perineal infection could be treated in a traditional way.

Interpretation of results

89.4% of pts. are completely dry (0-1 pad). 7 patients (10.6%) evidenced postoperative complications with urethral erosion after an average of 192 days (21-430 days), reason why the sling had to be removed.

Concluding message

Our recent results are highly promising despite the selected negative circle, where over a 84.8% had previously been operated. For patients after irradiation treatment, bladder neck incision or endoscopically scarred urethras – "negative selection" – where Pro ACT® is not recommended as minimally invasive "first line" therapy, the Argus® sling is an interesting alternative.

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<b><i>Is this a clinical trial?</i></b>	<b>No</b>
<b><i>What were the subjects in the study?</i></b>	<b>HUMAN</b>
<b><i>Was this study approved by an ethics committee?</i></b>	<b>No</b>
<b><i>This study did not require ethics committee approval because</i></b>	<b>No ethics committee approval was required.</b>
<b><i>Was the Declaration of Helsinki followed?</i></b>	<b>Yes</b>
<b><i>Was informed consent obtained from the patients?</i></b>	<b>Yes</b>