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THE ARGUS(ADJUSTABLE SLING FOR TREATMENT OF ALL DEGREES OF MALE STRESS URINARY INCONTINENCE: RETROSPECTIVE EVALUATION OF EFFICACY AND COMPLICATIONS AFTER A MINIMAL FOLLOW-UP OF 14 MONTHS.

Hypothesis / aims of study
This is a retrospective study to evaluate the efficacy and complications of the Argus® for treatment of various degrees of male stress urinary incontinence (SUI).

Study design, materials and methods
Retrospectively, we evaluated continence (reported pads/24hrs), complications and Quality of Life (QoL) in 100 men SUI, who were consecutively treated with the Argus® between April 2005 and October 2008. Three groups were defined based on baseline incontinence: patients with mild incontinence using 1-2 pads/24hrs, moderate incontinence 3-5 pads/24 hrs, and severe incontinence >5 pads/day. The Argus® device is a suburethral silicone foam pad with two attached retropubic cone columns. The amount of urethral compression it provides can be regulated by adjustment of two silicone rings that rest on the rectus fascia. The sling was implanted as described by Romano et al. Patient evaluation included anamnesis, pad count, a QoL score, and Visual Analogue Scale (VAS) measurements to determine satisfaction with continence and with the surgical procedure. The results and complications were evaluated 6 weeks after surgery and in december 2009. Success was defined as cured: 0-1 security pad/24hrs and improved: 1-2 pads/24hrs (and pad reduction>50%).

Results
After a median follow-up (FU) period of 27 months (14-57 months), the Argus® was successful in 71% of patients. 13 patients were treated for mild incontinence, 46 for moderate incontinence and 41 for severe incontinence. Success rates stratified to degree of incontinence were 92%, 67% and 67% respectively. Revision procedures to provide more urethral compression were necessary in 32%, most often in severe incontinent patients (44%). Complications were registered meticulously and occurred in 55%, also most often in patients treated for severe incontinence. Most complications were self-limiting Clavien grade I-II and could be treated conservatively, for example perineal pain, urinary retention and bladder perforation during implantation. As grade III complications we registered infection (n=6), erosion (n=3), sling rupture (n=1), and irritative symptoms/pain (n=1) for which sling explantation was necessary, as well as urethral strictures for which surgical intervention was warranted (n=12). VAS measurements on continence and QoL.showed significant improvement. Patient satisfaction with treatment scored 7,8 at a scale of 1-10.

Interpretation of results
The Argus® adjustable male sling is most successfull (>90%) in patients with mild incontinence. In patients with moderate to severe incontinence success rates of more then 65% are accomplished in this study. Complications are not uncommon, but are mostly grade I-II. Overall, patients report significantly improved continence and QoL after treatment.

Concluding message
The Argus® adjustable male sling is a valuable adjunct in the treatment of all degrees of SUI.
We will continue follow-up of the patients in this study to evaluate durability.

Specify source of funding or grant	**none**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**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	**retrospective descriptive cohort study**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**