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Naumann G[1], Hagemeier T[2], Zachmann S[3], Al-Ani A[4], Skala C[1], Albrich S[1], Koelbl H[1]
1. *Department of obstetrics and gynaecology, Johannes Gutenberg-Universität Mainz, Germany,* ***2.*** *Pelvic floor center, Klinikum Suhl, Germany,* ***3.*** *Department of Obstetrics and Gynecology,Spital Maennedorf, Switzerland,* ***4.*** *Department of urology, Hufeland-Klinikum Bad Langensalza, Germany*

AJUSTTM FULLY ADJUSTABLE SINGLE INCISION SLING FOR THE TREATMENT OF STRESS URINARY INCONTINENCE: 1 YEAR FOLLOW-UP ON A NEW MINIMAL-INVASIVE TREATMENT FOR FEMALE SUI

Hypothesis / aims of study
Suburethral slings achieve excellent success with high continence rates in stress urinary incontinence. Conventional retropubic or transobturator tapes actually are preferred by most surgeons, but shows side effects and complications because of the blind passage of the tape. The single incision sling Ajust^{TM} has eliminated the need for blind trocar passing, utilizing a single vaginal incision and a push-in technique and allows a post-insertion bi-directional adjustability (loosen and tighten) after strong anchoring in obturator membrane.
This study evaluates the efficacy and safety of this new procedure with 1 year clinical outcome.

Study design, materials and methods
In our prospective, single-arm, observational study 52 patients with a mean age of 62.8 years (range 39-88 yrs.) were treated from November 2008 to March 2009 with Ajust^{TM} in 4 centres. All patients showed a stress urinary incontinence grade II and III. 2 patients had previous failed surgery for incontinence (1 colposuspension, 1 bulking agents). Each patient had a fully urogynecological assessment preoperatively with clinical examination, urodynamics and pelvic floor ultrasound. There was no combination with prolapse repair; the sling implantation was performed under local, general and spinal anesthesia in 27 (51.9%), 24 (46.2%) and 1 (1.9%) subjects, respectively.
The postoperative rate of continence was to be evaluated using a standardized cough stress test, Quality of Life was to be assessed using Kings Health Questionaire, Patient Perception of Intensity of Urgency Scale (PPIUS), Visual Analog Score (VAS) from 0 (worst) to 10 (best) for pain and global satisfaction and short form of UDI 6 and IIQ7.

Results
These are first results after 1 year of 52 patients. In all but 1 case the placement procedure took less than 30 minutes. The mean length of stay in the hospital was 2.2±0.67 days (range 1 to 5 days). All but 1 (98.1%, 51/52) of the Ajust Sling placement procedures was initially successful, changing in 1 case intraoperatively to TOT system. In one additional case sling had to removed after 2 weeks due to dislocation. No complication of bleeding >200 ml, bladder lesions, erosions, perforations, penetrations, protrusions, hematomas or bladder outlet obstructions occurred during the period covered by this analysis. Residual volume of urine reached not more than 50 ml. Overall, out of the 50 subjects who successfully received the Ajust Sling, 45 subjects demonstrated total restoration (86.5%) of their continence, 1 subject demonstrated improvement (1.9%) and 5 subjects failed (1 Alzheimers Disease with indwelling catheter, 1 apoplexy, 1 subject with new sling in case of reccurrent incontinence) (9.6%).
All patients described the postoperative phase as completely painless, after 12 months we didn't see any case of dyspareunia or other pain.

Interpretation of results
The study has no reported patient complications of bleeding, bladder lesions, erosions, perforations, penetrations, protrusions, hematomas or bladder outlet obstructions that occurred during the study.
Overall, 92.0% (46/50) of the subjects who successfully received the Ajust Sling demonstrated improvement or total restoration of their continence.
Remarkable is the painless procedure and postoperative period without any groin pain or dyspareunia.

Concluding message
First results showed a high efficacy with excellent continence rates because of the strong anchoring in the obturator membrane and high safety without severe side effects in fact of using a small mini-sling and possibility of bi-directional adjustability after insertion.
Further prospective studies with a longer follow-up have to prove the high efficacy.

Specify source of funding or grant	**no**
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 ethics committee approval because	**clinical use of a CE certified surgical product**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**