CONCLUSIONS: At one year follow-up, Mini-Arc© presents better outcomes compared to TVT-O© and TVT-Secur©. Mini-Arc© resulted in a lower rate of de novo stress urinary incontinence and a lower percentage of failures at the first follow-up. None of the complications were severe or led to the removal of the product.

Source of Funding: None

1769
RANDOMIZED CLINICAL TRIAL COMPARING TVT-O©, TVT-SECUR© AND MINI-ARC©: OUTCOME AT ONE YEAR FOLLOW-UP
Francisco Botelho*, Rui Oliveira, Pedro Silva, Carlos Silva, Francisco Cruz, Paulo Dinis, Oporto, Portugal

INTRODUCTION AND OBJECTIVES: Retropubic or transobturator mid-urethral slings are gold standard treatments for female stress urinary incontinence (SUI). Mini-slings have recently been introduced to lessen surgical morbidity and complications, but data about their outcome are sparse. Our objective is to compare success rates, complications and patient satisfaction at 12 months follow-up of the transobturator sling TVT-O© and the mini-slings, TVT-Secur© and Mini-Arc©.

METHODS: Ninety patients with urodynamic proven SUI were randomized, 30 to each arm, TVT-O©, TVT-Secur© (hammock) or Mini-Arc©. Patients with previous treatments for SUI or vaginal prolapse grade II or higher (PoP-Q) were excluded. Written informed consent was obtained. Groups were similar in mean age, body mass index, parity, severity of SUI, Valsalva Leak Point Pressure and duration of SUI. Patients were assessed in the pre-operative, first 24 hours, and at 1, 6 and 12 months after the procedure. King’s Health Questionnaire (KHQ) was used to evaluate patient satisfaction.

RESULTS: At 12-month evaluation, percentage of patients cured and improved were 83% and 10% after TVT-O©, 67% and 13% after TVT-Secur© and 87% and 6% after Mini-Arc©, respectively (p=0.188). Percentage of failures was 7% after TVT-O© and Mini-Arc© and higher, 20% after TVT-Secur©. In the multivariate analysis, sling type was the only statistically significant independent predictor of cure, TVT-Secur© being the one associated with lesser chance of cure (p=0.011). Mean pain score in the first 24 hours (0-10 Visual Analogue Scale) was 4.5±2.6 after TVT-O©, 2.3±2.3 after TVT-Secur© and 1.0±1.0 after Mini-Arc© (p<0.01). In the TVT-O© group there were 2 cases of urinary retention, requiring sling section. The mini-sling groups had 1 case of transient urinary retention each. There was 1 case of lower urinary tract infection in each of the mini-sling groups. Five patients after TVT-O© and 3 in each mini-sling groups had de novo moderate urgency. Prolonged thigh pain occurred in 2 patients after TVT-O© and in 1 after Mini-Arc©. There were no cases of pelvic organ injury, severe bleeding or sling exposure. KHQ scores expressed a significant improvement in quality of life in all groups.

CONCLUSIONS: At one year follow-up, Mini-Arc© presents identical outcomes to a standard transobturator technique but with fewer complications. TVT-Secur© success rate at 12 months follow-up is inferior to the two other slings. Nevertheless, larger randomized clinical trials with longer follow-up are warranted.

Source of Funding: None

1770
MIDDLE-TERM ASSESSMENT OF TVT-SECUR© FOR THE TREATMENT OF FEMALE STRESS URINARY INCONTINENCE
Pedro Silva*, Rui Oliveira, Alexandre Resende, Francisco Botelho, Carlos Silva, Paulo Dinis, Francisco Cruz, Oporto, Portugal

INTRODUCTION AND OBJECTIVES: TVT-Secur© was the first single-incision vaginal mini-sling designed to reduce morbidity associated with mid-urethral slings for treatment of female stress urinary incontinence (SUI). Until now, only short-term evaluations were reported. The objective is to describe our experience with this mini-sling at a mean follow-up of 30 months.

METHODS: Between October 2006 and August 2007 TVT-Secur© was placed in 107 women with predominant SUI (mean age - 55 years, mean parturition - 2). The mesh was put in the hammock position in all cases, through a 1 cm vertical incision starting 1 cm below the urethral orifice. A previous report, with a mean follow-up of 15 months, addressed surgical complications, cure and improvement rates, King’s Health Questionnaire score (KHQ) and appearance of de novo lower urinary tract symptoms. At the present, with a mean follow-up of 30 months, patients previously cured or improved were reassessed by a telephone interview, where they responded to the Patient Global Assessment of Improvement (PGI-I), rated their improvement in a 0-100 scale and answered if they would recommend the procedure to a friend.

RESULTS: At 15 months follow-up we had 75 patients cured (71%) and 15 improved (14%). At the present, with a mean follow-up of 30 months, 64 patients (71%) could be contacted. Five were excluded because of a major change in their health condition that impaired the assessment of their lower urinary tract condition. Subsequently, 49 previously considered cured and 10 improved were available for analysis. Thirty-nine of the cured patients (80%) rated the improvement of SUI by the PGI-I as “Very much better” or “Much better” and 8 (16%) considered to be “A little better”. One patient (2%) answered “No change” and another (2%) “A little worse”. The mean rate of improvement in a 0-100 scale was 81±18, 40 patients (82%) rating improvement ≥70. Forty-six (94%) would recommend this procedure to a friend. When analysing improved patients (n=10), 5 (50%) considered their PGI-I as “Very much better” or “Much better”, 3 (30%) “A little better”, 1 (10%) “No change” and 1 (10%) as “A little worse”. 6 patients (60%) rated equal or superior to 80% their improvement in a 0-100 score, and 8 (80%) would recommend the procedure to a friend. KHQ scores indicated that the improvement previously found remained unchanged.

CONCLUSIONS: This study shows that the majority of patients cured after TVT-Secur© remained satisfied at a middle term follow-up.

Source of Funding: None

1771
ARE WE OBSTRACTING OUR PATIENTS TO CURE THEIR INTRINSIC SPHINCTERIC DEFICIENCY INCONTINENCE?
URODYNAMIC RESULTS BEFORE AND AFTER A REMEEX RE-ADJUSTABLE SLING
Carlos Errando*, Cristina Gutierrez, Fernando Rodriguez-Escobar, Carlos Baez, Pedro Araño, Humberto Villavicencio, Barcelona, Spain

INTRODUCTION AND OBJECTIVES: To clarify if the patients cured of intrinsic sphincteric deficiency (ISD) with a RemeeX re-adjustable sling were urodymanically obstructed. We quantified the differences in the urodynamic parameters of obstruction before and after the surgery and secondarily compared between patients that were cured and not cured of their incontinence.

METHODS: Eighty-three patients were classified as having an ISD if they accomplished the following criteria: leak at rest or minimal stress, no urethral hipermobility, and maximal closure pressure of less than 20 cm of water (urethral pressure profile). All females underwent a re-adjustable sling. Contience was defined as negative cough and pad-test. All patients had a urodynamic evaluation before and after the...
surgery. The variables studied were maximal flow rate (Qmax) in the uroflowmetry, urethral resistance factor (URA), maximal flow rate and detrusor pressure at maximal flow rate (PdetQmax) in the pressure-flow study (PFS). The variables were compared using the Student’s t-test or Wilcoxon rank test.

RESULTS: After a mean follow up period of 53 months, 70 patients (84%) achieved cure of stress incontinence. Thirteen patients (16%) remain incontinent. Twenty-two cases (26%) required adjustment of the sling after the initial procedure. The Qmax in the uroflowmetry and in the PFS showed a statistically significant decrease after the surgery in cured patients. The PdetQmax increased significantly after the procedure in continent patients. The URA did not show a statistically significant change. The clinical significance of these changes could be considered as marginal. The comparison of the changes in these parameters between the patients cured or not of the incontinence was not significant. The Qmax in the uroflow and PFS, PdetQmax and URA after the procedure were not significantly different in patients continent compared with the incontinent cases.

CONCLUSIONS: The re-adjustable sling provides a good cure rate in the case of ISD incontinence, with no evidence of obstruction. Even though the continent patients showed a decrease in almost all the urodynamic parameters of the voiding phase, the clinical significance of these changes can be considered minimal.

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Source of Funding: None

1772
WHAT CAN WE LEARN FROM EXPLANTED SLINGS AND MESHES IN PELVIC FLOOR SURGERY?

Ruth Kirschner-Hermanns*, Uwe Klinge, Aachen, Germany; Bernd Klosterhalfen, Dueren, Germany; Bernhard Brehmer, Axel Heidenreich, Aachen, Germany

INTRODUCTION AND OBJECTIVES: In the last 10 years implantation of slings and various textile meshes have become standard procedures in continence and female pelvic floor surgery. In contrast to hernia surgery with much longer experience knowledge of requirements for mesh material best used for incontinence and prolapse surgery is still vage. Although the intention is to implant a tensionfree sling many studies show that urethral obstruction and erosion through the urethra over time are still the most feared complications after implant of mesh material and even after TVT or TVT-O slings We analysed more than 200 explants of different materials and structures of polypropylene (PP), polyester (PET), polytetrafluorethylene (PTFE), polyvinylidenfluoride (PVDF) used for incontinence and prolapse surgery.

METHODS: All explanted structures were examined by extensive histological tests, such as: 1. estimation of the foreign body reaction and fibrosis 2. induction of erosions, and 3. possible induction of chronic pain by damage of peripheral nerve structures (neurora or pseudoneurora formation). Furthermore all explanted devices were characterized by various textile property tests, which were related to the fibrotic incorporation seen at the devices that had been explanted from humans.

RESULTS: Altogether, each implant indicated a typical foreign body reaction in the interface with an accumulation of epithelial macrophages and multinucleated foreign body cells. The outer layer of the foreign body granuloma was formed by a layer of connective tissue. In small porous meshes the average thickness of the granuloma was 37±μm±6μm vs. 21μm±4μm in large porous meshes. Erosions were common findings in 66±9% vs. 41±11% in the small vs. large porous group, respectively. Chronic pain and nerve damage with neuroma or pseudoneuroma formation were related to pore size and revealed 24±8% vs. 11±6% in the small vs. large porous.

CONCLUSIONS: Because of the marked inflammatory reaction of small pore structures, textiles with large pore should be preferred. However, the materials has to withstand considerable mechanical strains, in particular without reducing its porosity. Standard polymers like PP and PET showed considerable high damage of structural integrity, which was not found with PVDF

Source of Funding: For two of the authors, Uwe Klinge and Bernd Klosterhalven- his work was part of a research projects with the FEG Textiltechnik, Aachen, funded by the Federal ministry of Education and Research BMBF Uwe Klinge – (research projects with Ethicon, Covidien and the FEG Textiltechnik, Aachen, the latter funded by the Federal ministry of Education and Research BMBF)

1773
LONGITUDINAL CHANGES IN URINARY INCONTINENCE SYMPTOM SEVERITY FOLLOWING TREATMENT IN WOMEN

Lauren Wallner*, Rodney Dunn, Edward McGuire, John Wei, Ann Arbor, MI

INTRODUCTION AND OBJECTIVES: Urinary Incontinence (UI) is a prevalent condition affecting aging women that is associated with significant morbidity. While treatment strategies exist for UI, validated assessment of their efficacy with regard to symptomatic improvements following treatment are limited. Therefore, the goal of this study was to determine the change in symptom severity following treatment for UI in women using the Incontinence Symptom Index (ISI).

METHODS: 86 women, ages 18 or older, presenting with a primary complaint of UI who were treated using either surgery alone, surgery plus medication/behavioral therapy or medication/behavioral therapy alone were followed for two years post-treatment. Baseline and follow-up questionnaires ascertained UI symptom severity before and after treatment using the ISI, a validated, 10-item self-administered questionnaire that includes domains assessing stress UI, urge UI and bother. An incontinence ratio score, comparing stress to urge severity was estimated (SUI/(UUI+SUI)) and reflects whether someone has more stress, more urge, or mixed UI. A value of 1 indicates pure stress UI and a value of 0 indicates pure urge UI. Multivariable mixed models were used to estimate the change in total ISI and the three ISI sub-domains following treatment across treatment groups, adjusting for baseline symptom severity.

RESULTS: Women were on average 57.5 years old, followed for a mean 9.4 months and reported a median baseline total ISI score of 17.0. Total symptom severity after treatment significantly improved within all treatment groups after adjustment for baseline symptoms (all p < 0.05). Stress symptoms improved within the surgical group (p = 0.001) and surgery + behavioral/medication group (p = 0.02) but not the behavioral/medication group (p = 0.61). Urge symptoms improved only in the behavioral/medication group (p = 0.01). The ratio of stress to urge symptoms changed significantly in the surgical group only (p = 0.001). (See figure)

CONCLUSIONS: Our results suggest that overall UI symptoms significantly improve following treatment for UI but the type of incontinence symptom improvement depends on the type of treatment. These data demonstrate sensitivity of the ISI to changes in the type of UI