TRANS-OBTURATOR TAPE (T.O.T)TM FOR FEMALE STRESS URINARY INCONTINENCE : PRELIMINARY RESULTS OF A PROSPECTIVE MULTICENTER REGISTER.

Aims of Study
Evaluation of the results and complications of a new minimally invasive surgical technique using a Trans-Obturator Tape T.O.T™ (Uratape®).

Methods
165 consecutive patients with Stress Urinary Incontinence were recruited by 7 centres from November 2001 to January 2003. Inclusion criteria : Stress Urinary Incontinence, urethral hypermobility with or without previous surgery, and with or without associated prolapse. Pre-operatively history, physical examination, urodynamic testing and residual were evaluated. The post-operative evaluation was: physical examination, uroflowmetry and residual. Mean age was 57 years (29-87). 100/165 (60.6%) patients had pure stress urinary incontinence, and urge incontinence was associated in 65/165 patients (39.4%). 24/165 patients had recurrent Stress Urinary Incontinence. 9/165 patients had urethral closure pressure <20 cm of water. Anaesthesia was general for 115 patients and spinal for 50 patients. Objective and subjective criteria of voiding dysfunction were analysed at one year follow up: Qmax<15ml/s, residual volume >100 ml, symptoms of voiding dysfunction.

Results
Mean follow up was 5 months (1-16). At 6 months follow up 60/73 patients were completely cured (82.2%), 5/73 were significantly improved (6.8%) and 8/73 failed (9.5%). 4/100 patients (4%) complained from de novo urgency. Per-operative complications : no complication for 161/165 patients (97.5%), 1 bladder perforation, 2 urethral perforations and 1 vaginal perforation (lateral). Immediate post-operative urinary retention: 4/165 patients (2.4%); 2 required tape release 10 days after the implantation, and 2 had spontaneous recovery (self intermittent catheterisation during 6 and 90 days respectively). 6 vaginal erosions were diagnosed between 4 and 11 months. In all cases removal of the silicon part was followed by total recovery. 1 urethral erosion was observed at 4 months follow up. 5 patients (3%) complained from transient pain: 3 on the tunneler insertion site and 2 due to the operating position.

Conclusions
This new minimal invasive procedure is an effective and promising technique for the surgical treatment of female Stress Urinary Incontinence. The trans-obturator approach is a reproducible procedure with low per-operative complications. In particular there is no intestinal or vascular risk due to the perineal route. One bladder perforation occurred in the learning curve. The major risk is urethral perforation and it can be avoided by introducing the finger inside the vaginal incision until the finger tip is in contact with the tunneler. Then the tunneler is guided by the finger through the vaginal incision. The efficacy is comparable to other surgical treatments like retro-pubic route, but further follow-up is needed.

References