

## EFFICACY AND SAFETY OF A LOW ELASTICITY POLYPROPYLENE TRANSOBTURATOR MIDURETHRAL SLING IN THE TREATMENT OF FEMALE STRESS URINARY INCONTINENCE IN A LARGE MULTI-CENTER EUROPEAN REGISTRY WITH MID-TERM FOLLOW-UP.

### Hypothesis / Aims of Study

The aim of this ongoing observational registry is to investigate the efficacy and safety of a low elasticity polypropylene transobturator midurethral sling for the surgical treatment of female stress urinary incontinence (SUI) in a large patient population.

### Study Design, Materials and Methods

Patients who underwent the transobturator outside-in procedure as described by E. Delorme[1], with a monofilament polypropylene, light weight, macroporous midurethral sling (Aris™, Coloplast, Denmark) were prospectively followed at 16 centers in France, Belgium and Germany starting in July 2004. Inclusion criteria were: SUI, urethral hypermobility with or without previous surgery, and with or without associated prolapse. Pre-operative, operative and peri-operative data was recorded. The pre-operative evaluation included history, physical examination, urodynamic testing, and residual urine. Peri- and post-operative complications were recorded. Post-operative evaluations were performed according to the follow-up schedule at each individual center and included a physical examination, uroflowmetry and residual urine. Cure was defined as the absence of subjective complaint of urine leakage, improved as a decrease in stress incontinence, and failure as a lack of improvement or worsening of continence.

### Results

668 women underwent transobturator sling surgery. Full data sets are not available for each of these 668 patients; if the data in question is missing, the actual number of patients with the available data is specified. Patient characteristics included a mean age of 58.8 yrs (29–89 yrs), mean parity of 2.4 (0–11), 429/642 (66.8%) menopausal patients, 160/656 (24.4%) patients with prior hysterectomy, 75/649 (11.6%) patients that underwent previous prolapse surgery, and 65/649 (10.0%) patients with previous incontinence surgery. Of the 657 patients with available data on incontinence type, 317 (48.2%) patients had pure SUI, 245 (37.3%) had mixed incontinence, and 95 (14.5%) had SUI with urgency.

Type of anesthesia used included general in 345/646 (53.4%), spinal in 258/646 (39.9%) or local in 43/646 (6.7%) patients. Data on concomitant procedures was available for 163/655 patients, and included concomitant prolapse repair (n=87), concomitant hysterectomy (n=9) or both (n=30). Peri-operative complications consisted of bleeding > 300 mL (n=7), bladder perforations (n=4), urethral perforation (n=1), and vaginal perforations (n=20). Of the 668 total patients, no follow-up was available for 93 patients. Mean follow-up to date was 19.6 months (0.2-54 months), with 222 patients having at least 2 years of follow-up.

Short and mid-term efficacy of the midurethral sling procedure is shown in Table 1. Post-operatively, 364/527 (69.1%) had no urgency, urgency was reduced in 58/527 (11.0%), unchanged in 46/527 (8.7%), worse in 17/527 (3.2%) and de novo urgency was found in 42/527 (8.0%). Of the 575 patients with available follow-ups, complications included 6 (1.0%) defects of vaginal healing, 7 (1.2%) vaginal extrusions, 1 (0.2%) urethral erosion, and no bladder erosions.

**Table 1. Efficacy of Aris transobturator midurethral sling in the treatment of female stress urinary incontinence**

	<b>0-2 months (n=432)</b>	<b>2-6 months (n=240)</b>	<b>6-12 months (n=198)</b>	<b>12-24 months (n=137)</b>	<b>24-54 months (n=214)</b>
<b>Cured + Improved</b>	97.0%	94.6%	96.5%	92.7%	88.3%
<b>Cured</b>	85.9%	84.2%	85.9%	75.2%	73.8%
<b>Improved</b>	11.1%	10.4%	10.6%	17.5%	14.5%
<b>Failed</b>	3.0%	5.4%	3.5%	7.3%	11.7%

### Interpretation of Results

The results to date of this large European multicenter registry show that the Aris transobturator sling is a safe and effective treatment for female stress urinary incontinence. Efficacy is maintained over time, with cured and improved rates after two years comparable to the early post-operative results. In addition, there are low occurrences of de novo urgency and minimal occurrences of vaginal extrusions and urethral erosions.

#### Concluding Message

The results to date of this large European multicenter registry with continuing follow-up using a low elasticity polypropylene transobturator midurethral sling show that it is both safe and effective in the treatment of stress urinary incontinence. Long-term follow-ups are on-going in this registry, with an objective of obtaining 5 year follow-up data on the majority of patients.

#### References

1. Delorme E. Transobturator urethral suspension: a minimally invasive procedure to treat female stress urinary incontinence. Prog Urol 2001; 11:1306-13013

<i>Specify source of funding or grant</i>	Sites were compensated by Coloplast for site personnel time associated with data entry of follow-ups
<i>Is this a clinical trial?</i>	No
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	No
<i>This study did not require eithics committee approval because</i>	this is a multi-center observational European registry that was conducted in accordance with EU regulations. Patients underwent TOT surgery, and then were followed-up based upon standard hospital procedures (i.e. no additional procedures/tests were performed). Patients signed consent for the surgery, and were provided with letters informing them of the use of their anonymous data, with the right of opposition as well as the right to withdraw their data at any time from the registry.
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes