

Zutshi M<sup>1</sup>, Culligan P<sup>2</sup>, Fenner D<sup>3</sup>, Lucente V<sup>4</sup>, Nihira M<sup>5</sup>, Mellgren A<sup>6</sup>

1. Colorectal Surgery, Cleveland Clinic Foundation, Cleveland, Ohio, 2. Urogynecology and Reconstructive Pelvic Surgery, Atlantic Health System, Summit, NJ, 3. Urogynecology, University of Michigan, Ann Arbor, MI, 4. The Institute For Female Pelvic Medicine, Allentown, PA, 5. Division of Female Pelvic Medicine and Reconstructive Surgery, University of Oklahoma, Oklahoma City, OK, 6. Colorectal Surgery, University of Illinois, Chicago, IL,

**THE TOPAS™ SYSTEM FOR FECAL INCONTINENCE : A CLOSE LOOK AT COMPLICATIONS**

Hypothesis / aims of study

Recent litigation surrounding the use of synthetic mesh in reconstructive pelvic surgery has prompted increased scrutiny in the use of a new product.

Aim. This study aimed to look specifically at complications during a FDA regulated multicenter trial which utilized a Type 1 polypropylene mesh used as a transobturator posterior anal sling [TOPAS] for treating fecal incontinence.

Study design, materials and methods

After individual site IRB approval and informed consent, 152 patients at 14 centers underwent implantation. Adverse events were determined if device or procedure related. A DMC monitored all serious adverse events and adverse events and regulated whether these were related to the device or procedure or not.

Results

During the follow-up 117 treatment-related adverse events were reported over 2.8 years in 73 patients, and 110/117 deemed not serious. Seven serious adverse events were reported. (Table) No exposures, extrusions or organ perforations were reported. No patients withdrew due to a device-related complication.

The most frequent adverse event was pelvic-area pain (abdominal/buttock/groin/leg /pelvic/urogenital pain). Forty nine treatment-related pelvic-area pain adverse events were reported; 10 device related, 27 procedure related, and 12 related to both. One patient required surgery for sciatica. At 12 month post-implantation, the majority of patients were not bothered by the pain. Incision-site infection was reported in 9 patients (procedure related in 8). Two patients developed an abscess (1 device-related/1 required drainage). Four patients reported urinary incontinence (1 new and 3 worsening). Treatment-related bleeding was seen in 1 patient requiring no treatment. Two patients reported defecatory dysfunction (constipation). One patient developed a deep vein thrombosis. Pelvic organ prolapse needing surgery was seen in 7/9 patients.

Limitations: This is a case series with no control arm for comparison.

Interpretation of results

No mortality was reported. There were no infections that resulted in explantation of mesh, mesh erosion or extrusion. Pain was the most frequent AE. All other AE's are similar to AE's reported with mesh in the literature. Pain was transient in most patients A few patients with occult urinary incontinence may be symptomatic after implantation. Pelvic organ prolapse may need to be evaluated in all patients preoperatively.

Concluding message

No major complications related directly to the mesh were reported. Despite concerns regarding exposure/extrusion associated with mesh use, patients experienced neither complication. Pain at the implantation site or referred pain and the most frequently reported symptom and was transient in the majority of patients. The TOPAS system is a relatively safe procedure for the treatment of fecal incontinence when used by qualified trained personnel.

SAE	Days from Procedure	Duration (Days)	Device Related	Procedure Related	Intervention	Resolution
Prolapse Worsening	- 122	55	Yes	No	Robotic assisted laparoscopic rectopexy	Resolved without sequelae
Prolapse - New	433	100	Yes	No	Supracervical hysterectomy with bilateral salpingectomy, sacrocolpopexy,	Resolved without sequelae
Prolapse Worsening	- 190	180	No	Yes	Rectocele repair	Resolved without sequelae
Post Traumatic Stress Disorder	7 days prior	1330	No	Yes	Medication: Clonidine, Tegretol Inpatient rehabilitation therapy for 3 months	Ongoing
Deep Venous Thrombosis	21	10	No	Yes	Enoxaparin (Lovenox) Warfarin (Coumadin)	Resolved without sequelae
Other: Chronic Obstructive Pulmonary Disease	1	1	No	Yes	Furosemide Salbutamol Ipratropium Solumedrol	Resolved without sequelae

**Table : Serious adverse events and their sequelae**

<b>SAE</b>	<b>Days from Procedure</b>	<b>Duration (Days)</b>	<b>Device Related</b>	<b>Procedure Related</b>	<b>Intervention</b>	<b>Resolution</b>
<b>Infection (other than UTI): MRSA Infection</b>	58	117	No	Yes	Clindamycin, morphine, Valtrex, vancomycin, calcium channel blocker, topical nitroglycerin, antibiotics	Resolved without sequelae

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Disclosures

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