



The anatomy of Trans-Obturator Posterior Anal Sling (TOPAS) and dynamics of potential mechanism of action

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Abstract

Background The aim of this study was to investigate the course of the transobturator posterior anal sling and its relationship to anatomical structures.

Methods The transobturator anal sling procedure was performed in four fresh-frozen pelvises. The pelvises were dissected and the structures adjacent to the sling and the course of the sling were identified and measurements obtained.

Results The transobturator posterior anal sling was inserted 2 ± 0.5 cm posteriorly to the anus, and 2.5 ± 0.5 cm caudal to the coccyx under the levator plate at the level of the puborectalis muscle. The tape was 3.5 ± 0.5 cm from the pubic symphysis and 2.3 ± 0.3 cm from the obturator canal at entry into the pelvic cavity. The tape passed 2.3 ± 0.3 cm inferior–medial to the obturator canal. At entry, the sling passed lateral to the ischiopubic ramus through the following structures: gracilis, adductor brevis, obturator externus, obturator membrane, and beneath the obturator internus muscle. The sling traveled $2–3 \pm 0.5$ cm over the iliococcygeus muscle and perforated the iliococcygeus fibers 0–2 cm medial to arcus tendinous levator ani. The posterior division of the obturator nerve was 2.8 ± 0.7 cm from the tape. The anterior division of the obturator nerve was 3.4 ± 0.8 cm from the tape. The device passed 1.1 ± 0.4 cm from the most medial branch of the obturator vessels.

Conclusions The transobturator posterior anal sling travels mostly in the avascular area of the ischioanal fossa and posterior to the puborectalis muscle as intended.

Keywords Anatomy · Anal sling · Transobturator posterior anal sling · Fecal incontinence

Introduction

The term fecal incontinence (FI) describes an involuntary loss of bowel content including flatus, mucus, liquid and solid feces. It may result in severe social, hygienic, and psychological consequences [1, 2]. Systematic reviews indicate that FI affects 0.4–18% of the general population [2]. The prevalence of FI in the female population increases with age,

from 2% in younger patients to 20% in older patients [3, 4]. According to large population studies, the prevalence of FI among adult women in the United States is approximately 5–10%, with at least one monthly incontinent episode [4–7]. Nevertheless, due to the embarrassing nature of this condition, it is underreported by patients and health providers, which makes it difficult to determine the real prevalence of this condition [8]. In one study by Bliss and colleagues, more than one-third of patients with FI had not discussed their condition with a health care professional [9]. FI has devastating social and emotional effects on patients, including shame, embarrassment, depression, anxiety, and social isolation [1, 10, 11]. The etiology of FI is multifactorial; it is often caused by a combination of abnormalities including congenital, anatomical, neurological, and functional abnormalities [8]. Thus, no standard treatment regimen exists for patients with FI. The traditional first-line therapy is conservative management including dietary modification, pharmacologic intervention, and/or pelvic floor muscle training. Patients who fail conservative management may pursue

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a surgical sphincteroplasty, injection of bulking agents [12], and sacral nerve stimulation [13, 14]. Placement of an artificial bowel sphincter no longer available for this indication [15], and percutaneous tibial nerve stimulation is not Food and Drug Administration (FDA) approved for FI [16].

Unfortunately, despite these techniques, the outcomes in patients with FI remain suboptimal, and additional treatments are needed. Therefore, a new device, the transobturator posterior anal sling (TOPAS) for the treatment of FI was introduced by Rosenblatt et al. [17]. TOPAS was a sterile, single use, minimally invasive, self-fixating polypropylene mesh. The TOPAS System consisted of two insertion needles and one mesh sling assembly. An FDA panel unanimously recommended approval of the TOPAS device in February 2016, but less than 1 week later, the company manufacturing the device (Astora Women's Health, formerly known as American Medical Systems) was shut down by its parent company, Endo Pharmaceuticals, as a result of vaginal mesh litigation. Shortly thereafter, the premarket approval (PMA) application for TOPAS was withdrawn before formal FDA approval was received. There are efforts currently under way to bring TOPAS back on the market, which makes the description of the anatomical path of the TOPAS clinically relevant. Although the exact anatomical path and mechanism of action of TOPAS is unknown at the present time, it most likely reinforces the normal anatomical relationship between the rectum and anus and facilitates the normal closing mechanism by enhancing focal structural support [17, 18]. No previous anatomical dissections of the course of posterior anal slings have been published to help the practitioner conceptualize the structures that lie in the path of the sling. A search of the literature from January 1980 to November 2018 using the National Library of Medicine's MEDLINE database, including but not limited to the search terms "anatomy", "transobturator posterior anal sling", and "posterior anal slingplasty", did not find any reports of the description of the surgical anatomy of posterior anal slings.

The goal of this study was to follow and describe the anatomical path of TOPAS and the adjacent structures in fresh-frozen pelvises to identify neural and vascular structures that are in the path of the sling when clinically applied.

Materials and methods

This was an anatomical observational study that was approved as an exempt study at Inova Fairfax Hospital. During the period March–November 2018, the TOPAS procedure was performed in a manner similar to that described by the TRANSFORM study group [18].

The procedure was performed in four fresh-frozen pelvises. Exclusion criteria Included: evidence of rectal prolapse, known history of FI, vaginal surgery, retropubic

surgery, and anal surgery. The pelvises were drawn equally from two Caucasian and two African-American female cadavers without a history of a hysterectomy or pelvic surgery. Although the pelvises appeared to be from middle-aged women, the details of their demographics, such as precise age, parity or the cause of death, were not available to us.

Since the TOPAS device is not in production, we used an Apogee needle (AMS Corp.), which is identical to the TOPAS needle, and 2 × 12 cm strips of Restorelle mesh (Coloplast Inc., Minneapolis, MN, USA) to perform the procedures as previously described (Fig. 1). The first step was marking the two buttock incisions' sites, 2 cm lateral and 3 cm posterior to the mid-anal verge, which should correspond to a point half-way between the anus and coccyx. The two marks should not be more than 5 cm apart. Then, we marked the medial border of the obturator foramen, along the descending ischiopubic ramus, at the level (or slightly above) the urethra. The two 1–1.5-cm vertical



Fig. 1 Apogee needle (AMS Corp.) and 2 × 12 cm strips of Restorelle mesh (Coloplast Inc. Minneapolis, MN, USA); was used to perform the transobturator posterior anal sling procedure as described in the methods

buttocks incisions were then performed in the previously marked areas. A dissection was done between the two buttocks incisions creating a tunnel posterior to the anal sphincter and puborectalis muscle and approximately 2 cm deep to the perianal skin, while placing the index finger of the non-dominant hand in the rectum to protect the rectum from injury. The sling was then passed through the tunnel we created. The next step was making a stab incision at the marked medial border of the obturator foramen, to pass the TOPAS needle tip through this incision, with the needle tip passing perpendicular to the obturator membrane creating a tunnel towards the buttock incisions performed previously, the index finger of the non-dominant hand should be in the vagina first and then in the rectum as the needle tip gets closer to the buttock incision. Afterwards, the mesh edge of each side was attached to the TOPAS needle, and pulled through the tunnel to exit the obturator incisions. Tensioning of the device was completed by pulling the mesh upward together until gentle tension was palpable by digital rectal examination. The perianal skin incisions were closed and the excess mesh was removed from the obturator incision site [18].

After the placement of the TOPAS sling, the pelvis were dissected first by dissecting the obturator region and then the posterior rectal and ischioanal fossa to investigate the sling's relationship to the bony pelvis, the musculature of the pelvis, the pelvic nerves, the neurovascular bundle in centimeters (cm) and expressed as mean \pm standard deviation (SD). To investigate the relations between the sling and the structures in the obturator space, we dissected the external obturator region in the lithotomy position in leg stirrups. Prone dissections were made to look at the relationship of the sling to the neurovascular structures that lie posterior and lateral to the levator ani muscles (LAM), and the relations with surrounding neuro-vessels around the rectum.

Results

The tape passes around the ischiopubic ramus. The distance from the device to the obturator canal was on 2.3 ± 0.3 cm (range, 2.0–2.6 cm) and the tape passes, in order, through the following structures: gracilis, adductor brevis, obturator externus, and obturator membrane, beneath or through the obturator internus muscle.

The device passed 2.3 ± 0.3 cm (range, 2–2.6 cm) inferior–medial to the obturator canal. The posterior division of the obturator nerve was 2.8 ± 0.7 cm (range, 2.1–3.5 cm) from the transobturator device. The anterior division of the obturator nerve was 3.4 ± 0.8 cm (range, 2.7–4.5 cm) from the transobturator device. The transobturator device passed 1.1 ± 0.4 cm (range, 0.5–1.4 cm) from the most

medial branch of the medial division of the obturator vessels (Fig. 2).

The TOPAS was inserted 2 ± 0.5 cm (range, 1.5–2.5 cm) posteriorly to the anus, and 2.5 ± 0.5 cm (range, 2.0–3.0 cm) caudally to the coccyx. The tape was noted to be at the caudal inferior edge of the puborectalis muscle, and not passing through this muscle. The pubococcygeus (PC) muscle was medially reflected with instruments to show the laterally placed puborectalis muscle (PR) (Fig. 3). The relationship of iliococcygeus fibers to medially placed PC fibers and laterally placed PR muscle fibers is intricate. Three centimeters anteriorly, the sling and the PR crisscross with PC muscle.

The tape distance is located 3.5 ± 0.5 cm (range, 3.0–4.0 cm) from the pubic symphysis and 2.3 ± 0.3 cm (range, 2.0–2.6 cm) from the obturator canal. At the point of entry into the pelvic cavity, after exiting the obturator canal, the tape is situated medial to the iliococcygeus muscle, perforating through the arcus tendineus levator ani and slides over the medial aspect of the iliococcygeal muscle to perforate again through the iliococcygeal fibers to exit into the ischioanal fossa. The inferior rectal nerve

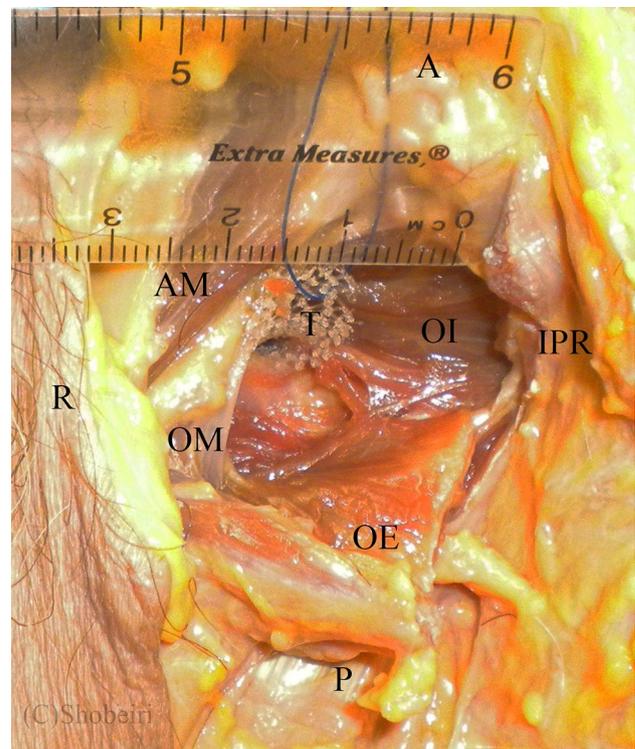


Fig. 2 Dissection of the external obturator region in the lithotomy position: The tape passes through: obturator externus (OE), and obturator membrane (OM), beneath or through the obturator internus muscle (OI), to pass around the ischiopubic ramus (IPR), R right, P posterior, T tape, AM adductor magnus muscle, OE obturator externus, OI Obturator internus, IPR Ischiopubic ramus

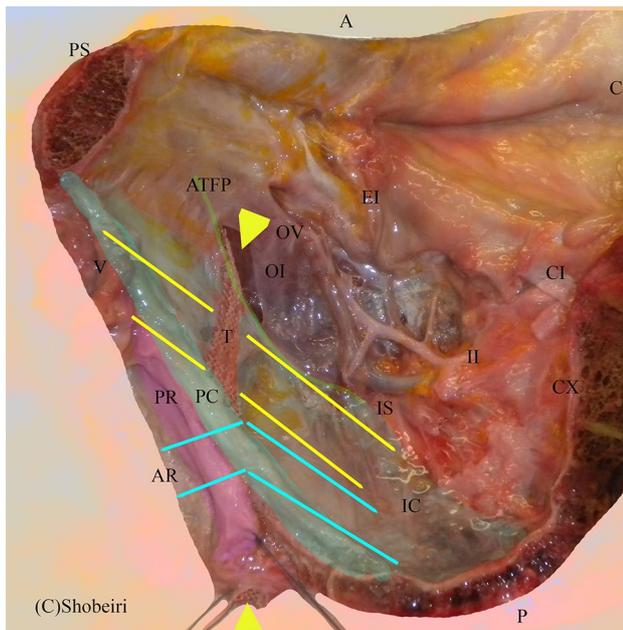


Fig. 3 Sagittal right hemipelvis: Viscera removed demonstrating the relationship of the tape (T) to the puborectalis muscle (PR), pubococcygeus muscle (PC), and the iliococcygeus muscle (IC). At the level of the anorectal junction, the sling perforates through the arcus tendineus fascia pelvis (AFTP) to slide over the medial aspect of the IC muscle, laterally to PR and PC, and perforates through the iliococcygeal muscle. Yellow arrows demonstrate the sling trajectory. A anterior, P posterior, C cephalad, PS pubic symphysis, V vagina, T tape, AFTP arcus tendineus fascia pelvis, OV obturator vessels, OI obturator internus, PC pubococcygeus, PR puborectalis, AR anorectum, IC iliococcygeus, IS ischial spine, CX coccyx, EI external iliac, II internal iliac

was noted to have variable nerve branching and dividing at various distances from the main pudendal nerve trunk.

Prone dissections were made to look at the relationship of the sling to the neurovascular structures that lie lateral and posterior to the LAM. First, cephalad to caudad dissection was made to isolate the pudendal nerve at the level of the ischial spine and find its distal branches. Second, lateral dissection of the sling was performed into the ischioanal fossa. The sacrotuberous ligaments were removed to expose the underlying pudendal nerve going into the Alcock's canal. The sciatic nerve was also noted. The S2 and S3 nerve roots were followed coming down through the sacral foramen to form the pudendal nerve, which enters the pelvis to innervate the pelvic floor. Alcock's canal was unroofed to expose the underlying pudendal nerve. The clitoral branch was followed, which is the most distal branch of the pudendal nerve. The puborectalis muscles were then removed to demonstrate the relationship of the sling to nerves and the anococcygeal ligament (Fig. 4).

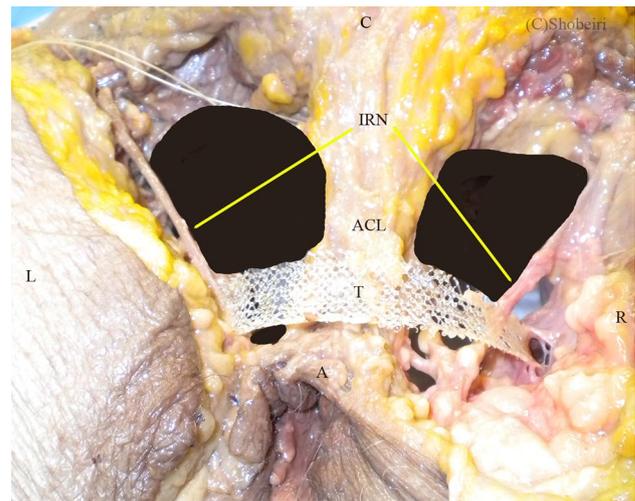


Fig. 4 Prone position of the pelvis: The puborectalis muscles have been removed to demonstrate the relationship of the tape (T) to the surrounding nerves and the anococcygeal ligament (ACL). The tape was inserted 2.5 cm posteriorly to the anus (A), passing underneath the ACL, and lateral to the inferior rectal nerves (IRN) (yellow arrows). L left, R right, C cephalad, T tape, A anus, ACL anococcygeal ligament, IRN inferior rectal nerve

Discussion

The main aim of the present descriptive study was to follow the anatomical path of the TOPAS, and to investigate the neurovascular structures that lie in the vicinity to minimize the risk for potential surgical injury in future use of the procedure.

Previous studies have shown that the pelvic floor muscles surround the urethra, vagina, anus and rectum in an intriguing series of belts. The puborectalis muscle forms a sling around and behind the rectum just cephalad to the external anal sphincter [19–22]. This muscle is responsible for the normal “anorectal angle,” which is thought to essentially create a “flap valve” between the rectum, where stool is normally stored, and the anus, where stool is passed during defecation. The original concept of TOPAS was to reinforce the normal anatomical relationship between the rectum and anus [17]. Rosenblatt et al. conducted a preliminary prospective study that recruited 29 women who had moderate FI and had TOPAS implantation. Overall, they reported a significant decline in the frequency of FU episodes and severity of FI symptoms as well as a significant improvement in quality of life among the study participants. There were no device-related serious adverse events (AEs) and no device-related erosions or extrusions [17]. Their results indicated that the TOPAS might be a potential novel therapeutic option for FI.

Those results were confirmed by Mellgren et al. [18], in a large, multicenter, prospective study, which was conducted to assess the efficacy and safety of the TOPAS in

treating FI under the rigors of a Food and Drug Administration (FDA)-approved investigational device exemption (IDE) protocol. The study enrolled a total of 152 women with FI who failed conservative treatments and were implanted with the TOPAS in 14 centers in the United States, and FI was assessed preoperatively and at the 12-months follow-up with a 14-day bowel diary, FI Quality of Life questionnaires, and Cleveland Clinic Incontinence Scores. Treatment success was defined as a decline in the number of FI episodes of 50% or more compared to the patient's baseline condition. The study showed that TOPAS provided significant alleviation of FI symptoms and quality of life with a reported success rate was 69.1% among patients at 12-months follow-up and complete continence in 19% of patients.

A total of 66 patients experienced 104 procedure- and/or device-related AEs. Most AEs were short in duration and 97% were managed without therapy or with nonsurgical interventions. No treatment-related deaths, erosions, extrusions, or device revisions were reported. The most common AE categories were pelvic pain ($n=47$) and infection ($n=26$). Those patients experiencing pelvic pain had a mean pain score of 1.2 (SD 2.4) (0–10 scale, 0 = no pain) during the 12-months follow-up [18]. Therefore, the authors concluded that this device may be used as a new minimally invasive therapy for patients with FI that have failed or did not tolerate conservative treatments.

A weakness of our study may be that we used a variation of the TOPAS from free cut mesh, not as originally designed in the trial. However, other variations of the TOPAS sling have been made with polypropylene mesh arms and the central segment substituted with pre-attached porcine dermis to avoid rectal ulcers [23].

The current study demonstrated that TOPAS may have the same obturator-related complications as the other transobturator devices, but obturator-related pain was insignificant in the clinical trials. This may have to do with a different trajectory of the mesh once it is inserted. Another safety concern with the procedure is the possibility of injury to the posterior structures including the inferior rectal nerve and the cutaneous branches of the pudendal nerves, but again, inferior rectal nerve related pain was not observed in the clinical trial [18].

Conclusions

Although today the TOPAS device is yet to be FDA approved for clinical use, it is a likely future treatment option for patients with FI who have failed or do not tolerate conservative or other surgical treatments. In this study, we accurately investigated the anatomical trajectory of the sling through fresh cadaver pelvis dissection. Application of this knowledge can help us to conceptualize the anatomical

structures that lie in the path of the advancing trocar tip during surgery and hopefully avoid serious injuries to patients using TOPAS or similar kinds of slings in the future.

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Author contributions J. Alshiek: Project development, data collection, statistical analysis, manuscript writing. Peter Rosenblatt: Project development, manuscript review. S. A. Shobeiri: Project development, data collection, statistical analysis, manuscript writing.

Compliance with ethical standards

Conflict of interest Dr. Peter Rosenblatt is the inventor of the transobturator posterior anal sling the other authors declare that they have no conflict of interest.

Ethical approval This was an anatomical observational study that was approved as an exempt study at Inova Fairfax Hospital.

Informed consent For this type of the study, formal consent is not required.

References

1. C Norton (2009) Conservative and pharmacological management of faecal incontinence in adults. *Incontinence* 1321–1386
2. Macmillan AK, Merrie AE, Marshall RJ, Parry BR (2004) The prevalence of fecal incontinence in community-dwelling adults: a systematic review of the literature. *Dis Colon Rectum* 47(9):1341–1349
3. Brown H, Wexner S, Segall M, Brezoczky K, Lukacz E (2012) Accidental bowel leakage in the mature women's health study: prevalence and predictors. *Int J Clin Pract* 66(11):1101–1108
4. Whitehead WE, Borrud L, Goode PS, Meikle S, Mueller ER, Tuteja A et al (2009) Fecal incontinence in US adults: epidemiology and risk factors. *Gastroenterology* 137(2):512–517 e2
5. Melville JL, Fan M-Y, Newton K, Fenner D (2005) Fecal incontinence in US women: a population-based study. *Am J Obstet Gynecol* 193(6):2071–2076
6. Markland AD, Goode PS, Burgio KL, Redden DT, Richter HE, Sawyer P et al (2010) Incidence and risk factors for fecal incontinence in black and white older adults: a population-based study. *J Am Geriatr Soc* 58(7):1341–1346
7. Wu JM, Vaughan CP, Goode PS, Redden DT, Burgio KL, Richter HE et al (2014) Prevalence and trends of symptomatic pelvic floor disorders in US women. *Obstet Gynecol* 123(1):141
8. Johanson JF, Lafferty J (1996) Epidemiology of fecal incontinence: the silent affliction. *Am J Gastroenterol* 91(1):33–36
9. Bliss DZ, Fischer LR, Savik K (2005) Managing fecal incontinence: self-care practices of older adults. *J Gerontol Nurs* 31(7):35–44
10. Landefeld CS, Bowers BJ, Feld AD, Hartmann KE, Hoffman E, Ingber MJ et al (2008) National institutes of health state-of-the-science conference statement: prevention of fecal and urinary incontinence in adults. *Ann Intern Med* 148(6):449–458
11. Miner PB Jr (2004) Economic and personal impact of fecal and urinary incontinence. *Gastroenterology* 126:S8–S13

12. Mellgren A, Matzel K, Pollack J, Hull T, Bernstein M, Graf W et al (2014) Long-term efficacy of NASHA Dx injection therapy for treatment of fecal incontinence. *Neurogastroenterol Motil* 26(8):1087–1094
13. Matzel K, Stadelmaier U, Gall F, Hohenfellner M (1995) Electrical stimulation of sacral spinal nerves for treatment of faecal incontinence. *Lancet* 346(8983):1124–1127
14. Wexner SD, Collier JA, Devroede G, Hull T, McCallum R, Chan M et al (2010) Sacral nerve stimulation for fecal incontinence: results of a 120-patient prospective multicenter study. *Ann Surg* 251(3):441
15. Wong WD, Congliosi SM, Spencer MP, Corman ML, Tan P, Opelka FG et al (2002) The safety and efficacy of the artificial bowel sphincter for fecal incontinence. *Dis Colon Rectum* 45(9):1139–1153
16. Hotouras A, Murphy J, Walsh U, Allison M, Curry A, Williams NS et al (2014) Outcome of percutaneous tibial nerve stimulation (PTNS) for fecal incontinence: a prospective cohort study. *Ann Surg* 259(5):939–943
17. Rosenblatt P, Schumacher J, Lucente V, McNevin S, Rafferty J, Mellgren A (2014) A preliminary evaluation of the TOPAS system for the treatment of fecal incontinence in women. *Female Pelvic Med Reconstr Surg* 20(3):155–162
18. Mellgren A, Zutshi M, Lucente VR, Culligan P, Fenner DE, Chern H et al (2016) A posterior anal sling for fecal incontinence results of a 152-patient prospective multicenter study. *Am J Obstet Gynecol* 214(3):349 e1–e8
19. DeLancey JO (1988) Structural aspects of the extrinsic continence mechanism. *Obstet Gynecol* 72(3 Pt 1):296–301
20. DeLANCEY JO (1986) Correlative study of paraurethral anatomy. *Obstet Gynecol* 68(1):91–97
21. Oelrich TM (1983) The striated urogenital sphincter muscle in the female. *Anat Rec* 205(2):223–232
22. Shobeiri SA, Gasser RF, Chesson RR, Echols KT (2003) The anatomy of midurethral slings and dynamics of neurovascular injury. *Int Urogynecol J* 14(3):185–190
23. Brochard C, Queralto M, Cabarrot P, Siproudhis L, Portier G (2017) Technique of the transobturator puborectal sling in fecal incontinence. *Tech Coloproctol* 21(4):315–318

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