

## MASTER CLASS



CHARLES E. MILLER, M.D.

## The Transobturator Tape Procedure

In the August edition of Master Class, Dr. Mickey Karram discussed the use of tension-free vaginal tape (TVT) for the treatment of symptomatic stress urinary incontinence. Although both the success rate and subsequent patient satisfaction with TVT have proved to be excellent, the risk of bladder perforation re-

mains a concern. Because of this risk, I have continued to perform laparoscopic retro-pubic urethropexy (Burch procedure) for severe stress urinary incontinence.

In this edition of Master Class, the second-generation midurethral sling—known as the transobturator tape (TOT) procedure—will be discussed. This technique, when used in patients without internal sphincter deficiency and/or low urethral opening pressures, has proved to be not only efficacious, but safe as well. In my early experience, TOT has proved to be an easy procedure to master.

The TOT procedure can be performed

via two distinct approaches. I have asked Dr. Peter Sand to present the “outside-in” technique. Dr. Sand is professor of obstetrics and gynecology at Northwestern University, Chicago. He is the director of Evanston Northwestern Healthcare’s division of urogynecology and reconstructive pelvic surgery, as well as the director of the fellowship program in female pelvic medicine. Dr. Sand also directs the Evanston Continence Center.

Discussing the “inside-out” approach to TOT will be Dr. Vincent Lucente. Dr. Lucente is a clinical professor of obstetrics and gynecology at Temple University in

Philadelphia. He is the chief of gynecology at St. Luke’s Health Network in Allentown, Pa., and the medical director of the network’s continence management center. Dr. Lucente is also the chief medical officer of the Institute for Female Pelvic Medicine and Reconstructive Surgery in Allentown, as well as chief of the Section of Female Pelvic Medicine and Reconstructive Surgery at Abington (Pa.) Memorial Hospital. ■

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PETER SAND, M.D.

## Synthetic Midurethral Slings and the Attractiveness of TOT

It was not long after the use of tension-free vaginal tape (TVT) took hold in the treatment of stress urinary incontinence that experts began looking for an even safer approach to creating a midurethral sling.

The lure to the development of a second generation of midurethral slings lay in the small but still significant number of reported complications with the TVT procedure, in which a polypropylene mesh is placed through a vaginal-to-suprapubic route. The question loomed: Could reports of vascular injury, bowel and bladder perforations, and nerve injury with TVT be eliminated?

Dr. Emmanuel Delorme addressed the issue in 2001 by describing the first transobturator tape (TOT) procedure. In this approach, the sling is placed transperineally beneath the ischiopubic rami, rather than retro-pubically. It mimics the shape and function of the pubocervical fascia, forming a suburethral hammock of support.

Dr. Delorme’s idea was that if we could avoid passing needles through the retro-pubic space and instead insert the tape through a transobturator approach, we would have little or no chance of hitting the bladder or urethra—bladder perforations have occurred in approximately 3% of TVT procedures, according to reports—and we would alleviate the risk of bowel injury. Nor would we go near the abdominal vessels. Routine cystoscopy, moreover, might be unnecessary.

Today, transobturator tape (TOT) procedures are fast proving to be a safer—and at least equally effective—alternative to the original TVT procedure described by Dr. Ulf Ulmsten in 1996.

In the first randomized, prospective trial comparing TVT and TOT in approximately 60 patients, Dr. Renaud de Tayrac demonstrated that at 1 year, similar numbers of patients were cured and significantly improved (over 90%). Patients undergoing TOT, interestingly, had significantly lower postoperative rates of retention. They also had shorter operation times. And whereas bladder perforation occurred in almost 10% of the TVT patients, that complication affected none of the TOT patients.

(The de Tayrac paper was published in 2004 in the American Journal of Obstetrics and Gynecology, but it was later retracted, unfortunately, for lack of Institutional Review Board approval.)

Although longer-term data from prospective randomized studies are still forthcoming, additional studies of increasingly larger numbers of patients are clearly demonstrating that TOT offers comparable results to retro-pubic slings, with the benefit of lower complication rates and shorter operating times.

Some data suggest, just as Dr. de Tayrac’s work did, that TOT is also more forgiving with respect to voiding, and may be particularly preferable for patients with mixed incontinence or any symptoms of urge incontinence. It appears that TOT is less likely to impair bladder emptying, which, ironically, can be more problematic to patients than their original stress incontinence. The last thing we want to do is to alleviate the stress urinary incontinence only to induce or exacerbate any urge urinary incontinence.

There’s still a place for retro-pubic slings, however. Small trials have also shown that patients with intrinsic sphincter deficiency (ISD) have a higher success rate with the TVT procedure than with TOT, which makes sense when we consider the configurations of the two midurethral slings: the original retro-pubic sling’s U-shaped fit around the urethra, and the gentler hammocklike configuration of the transobturator sling. All told, TVT is significantly more effective than TOT when the urethral closure pressure while sitting with a full bladder is less than 43 cm H<sub>2</sub>O.

For most patients other than those with ISD, though, TOT now seems to be the preferable minimally invasive treatment. In addition to being safe and effective, it is easier to learn than the original TVT approach, especially for physicians who are not yet comfortable or experienced with the retro-pubic space.

Work on yet another generation of midurethral slings is advancing quickly, but physicians today are utilizing two TOT techniques: In the original technique—

coined the “outside-in” or “out-to-in” procedure (the technique described by Dr. Delorme)—the transobturator sling is placed inward through the obturator foramina from the labiocrural folds. The second technique—the newer version of TOT—involves placing the sling outward from the vaginal side toward labiocrural folds and, accordingly, is referred to as the “inside-out” or “in-to-out” TOT procedure.

The two techniques are quite different, and most physicians now favor one approach more than the other when they decide to perform TOT.

### Peter Sand, M.D.: The Outside-In Approach to TOT

For me, the outside-in approach, which uses a transobturator-to-vagina approach to mesh placement, is a logical choice. The TOT procedure was first described this way, and I have seen no need to deviate from it. It is simpler than the inside-out approach, and I see no logic to performing it the other way.

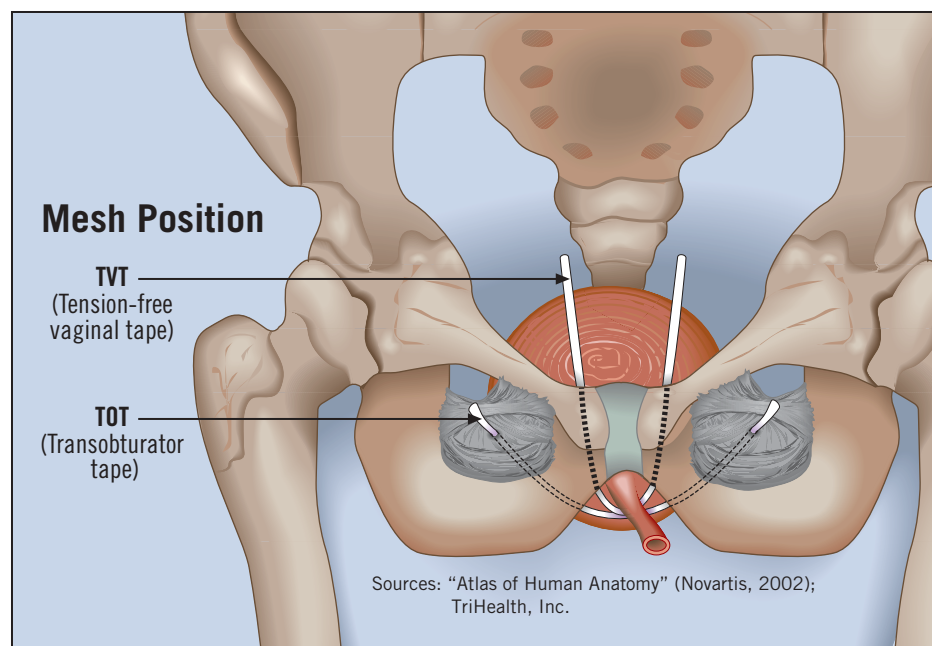
First of all, we know we’re improving outcomes with TOT in many women. In a retrospective cohort study comparing the TOT sling procedure (107 patients) with TVT (91 patients) at the Evanston Continence Center, we found that TOT resulted in significantly less postoperative retention and lower rates of de novo urge urinary incontinence.

Based on the results of 14-week postoperative urodynamic testing that was completed by about 66% of the patients, we found no significant difference in the percentage of patients cured of stress urinary incontinence (97% TVT vs. 90% TOT). And based on results of postoperative quality-of-life questionnaires, we concluded that subjective cure rates were similar between the groups (87% TVT vs. 89% TOT).

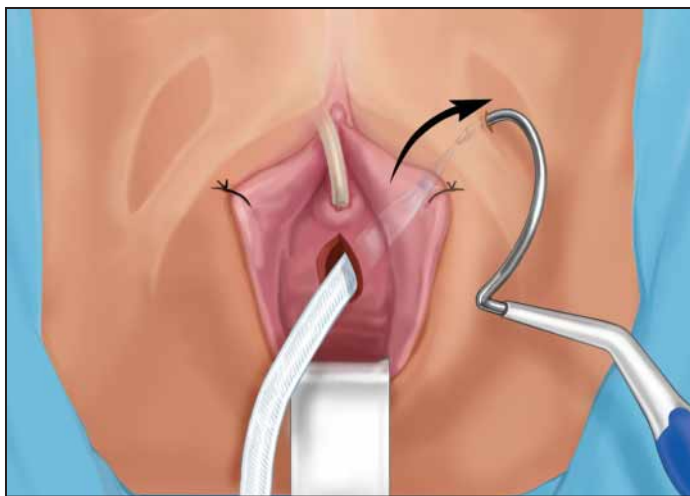
TOT did, however, offer the advantage



VINCENT LUCENTE, M.D.







In the outside-in TOT method, the sheath containing the polypropylene sling is attached to the Obtryx Halo, which is at the junction of the adductor longus and inferior pubic ramus.

of significantly less postoperative retention and lower rates of de novo urge urinary incontinence. Just as other data have shown, we've found that patients get back to normal voiding sooner with TOT. There was also a trend toward better resolution of urge urinary incontinence with TOT in these women with mixed incontinence symptoms.

Research suggests that we can achieve the same outcomes with either the outside-in or inside-out approach. Dr. Harry Vervest of Tilburg, the Netherlands, recently completed a randomized comparison of the outside-in and inside-out approaches in 75 women and found no significant differences in intraoperative or postoperative characteristics of the two procedures. Other studies have had similar conclusions.

Dr. Vervest looked at factors such as type of anesthesia, length of surgery, and amount of blood loss, as well as the length of catheter use and postoperative voiding parameters. He has reported that there were no complications with either method.

For me, however, the outside-in approach is a better choice. For one thing, I like to insert the needle where I have the most control. And overall, the outside-in approach is simpler than the other technique and does not result in the medial thigh pain that we hear about with the inside-out technique.

There are three different types of mesh-passer systems available. They use specially designed helical, curved, or hook needles. With each of these systems, the outside-in procedure involves three small incisions and the following essential steps:

A small vertical incision is made on the lateral edge of each labium majorum, medial to the labiocrural fold and posterior to the base of the adductor longus tendon. Once you identify the tendon, you'll find a depressed area that is the obturator foramen about an inch below the tendon. You can make a small stab wound on the medial edge of the obturator foramen bilaterally.

Another vertical incision is made on the anterior vaginal wall under the midurethra. You can dissect the vaginal epithelium from the underlying periurethral connective tissue, and then bluntly dissect under the vaginal epithelium about 2 cm bilaterally.

Then you can spread the scissors wide enough so that you can insert your index finger and point it toward one of the labiocrural incisions.

Starting with the right-side incision, you will angle your right index finger toward the incision in the labiocrural fold. The tip of the right-handed needle can then be pushed with your right thumb along the posterior surface of the ischiopubic ramus. You'll push through the obturator externus muscle, the obturator membrane, and the obturator internus muscle, feeling three separate pops before you feel the needle on your right index finger behind the endopelvic connective tissue.

Once you ensure that the needle is truly free of the overlying vaginal epithelium, you can connect the polypropylene mesh to the needle and rotate the needle back out through the obturator foramen. The same procedure can then be repeated on the other side.

To establish proper tension, I like to place a right-angle

clamp between the urethra and under the mesh and open it approximately 1 cm. I also check to ensure that the weave of the mesh below the urethra looks exactly like the weave of the mesh that exits through the labial incisions without any tension.

Some physicians use spacing devices, but I like to look at the mesh visually. If the mesh underneath the urethra does not look distorted and looks similar to the mesh protruding through the skin, then I know the sling is not under tension. I'll then go ahead and trim the mesh back against the skin and use simple sutures to close the incisions on each side.

The safety of this approach is ensured by fingertip guidance of the needle through the obturator membrane and the positioning of the index finger toward the incision and the cross-arm of the needle. This way, you're essentially opposing your thumb and index finger, ensuring proper passage of the needle.

Some physicians worry about the obturator canal's being several centimeters away from the path, but I believe that any injury would more likely occur through the inside-out approach.

Cystoscopy does not need to be performed routinely as it does with TVT, but the key here is the word "routinely." Whether or not cystoscopy is used is really dependent on the operator's judgment.

#### Vincent Lucente, M.D.: The Inside-Out Approach to TOT

The inside-out technique, which I use, was developed for the purpose of even further minimizing risk to the urethra and bladder and ensuring minimal dissection of the vaginal tissue.

Although Dr. Delorme's outside-in procedure was indeed a significant development for the treatment of stress urinary incontinence—and although most available studies show that the two approaches are similar in safety and efficacy—there have been several clinical reports and anatomical studies documenting that bladder and urethra injuries still occur with the technique.

This remaining potential for injury prompted Dr. Jean de Laval, of the University of Liège (Belgium), to develop an alternative TOT approach that he believed would be even safer because the TOT needle would travel out and away from the lower urinary tract.

I am convinced that his technique offers several advantages. For one thing, it essentially eliminates any risk of injury to the urethra and bladder. It also avoids potential injury to the anterior branch of the obturator artery, which runs around the outer perimeter of the obturator foramen. In the outside-in procedure, the instruments run along the edge of the foramen and can potentially disrupt that anterior branch. The hematomas that can occur—and there have been some reported—are not at all life threatening, but they can cause a protracted recovery for our patients.

I also believe that whenever we're traversing instruments through the body, we're always most accurate where we start our journey. By starting at the urethra and traveling away, I believe we're going to achieve more consistent and accurate placement of the sling at the midurethral position.

The greatest advantage to the inside-out technique, I believe, is one that has not been documented or well studied but still lingers in my mind. That is, because we need to do less periurethral dissection, we're minimizing the risk of urethral denervation.

The outside-in technique involves more periurethral dissection: One simply must dissect more tissue to assure the palpation guidance of the incoming instruments. Healing and re-ervation do occur, of course, but I believe the dissection inevitably increases the risk of sphincteric denervation, and that women may not get "back to baseline," so to speak—that they may suffer an insult that could lead later to ISD. It is quite possible that we are denervating the urethra musculature in subtle ways that cannot be measured now but will become apparent 10-15

years later as our patients age. I would rather avoid that possibility.

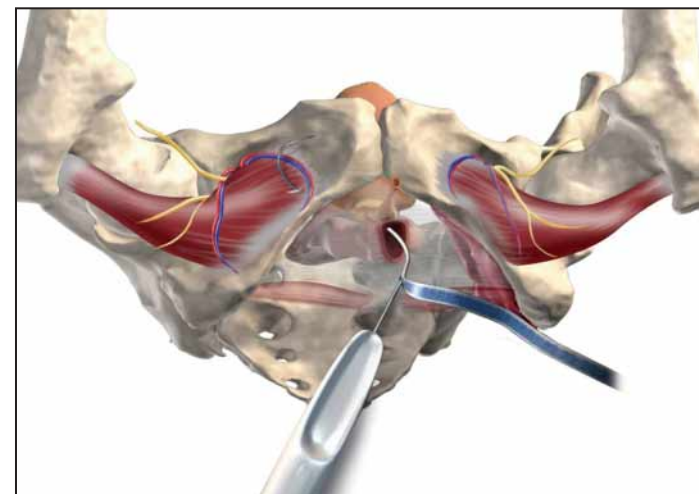
The key to the inside-out technique is the use of local anesthesia. The procedure enables us to use local anesthesia, fortunately, but it must be utilized thoroughly. Local anesthetic not only must infiltrate the area under the urethra and into the vagina, but it also must infiltrate the skin, fat, and—most importantly—the muscle of the inner thighs. With proper techniques, we can markedly reduce the likelihood of postoperative thigh pain.

The device used in the procedure includes a pair of helical passers that are assembled with polyethylene tubes bound to a polypropylene tape and one winged guide. The guide ensures that the tape will be passed accurately through the obturator membrane without entering the pelvic space.

The points where the needles will exit are identified by tracing a horizontal line at the level of the urethral meatus, and a second line 2 cm above this. The exit points are on this second line, 2 cm lateral to the folds of the thigh. We will make incisions at each exit point once the helical passer hits the skin; for now, we just mark the expected exit points and infiltrate with local anesthetic.

We then make a 1-cm long midline vaginal incision, starting 1 cm proximal to the urethral meatus. We dissect using a push-spread technique, orienting our scissors on a plane slightly above the horizontal, with a 45-degree angle relative to the urethral sagittal plane, toward the upper part of the ischiopubic ramus.

The winged guide is inserted into the tract at the same angle, until it passes the inferior pubic ramus. With the winged guide in place, a helical passer is then inserted into the tract. When the device is pushed slightly, the passer will move through the obturator membrane, at which point it is no longer advanced but rather is simply rotated and swung into position, which allows it to curve around the bone and exit through the thigh.



The inside-out TOT procedure aims to minimize dissection of vaginal tissue and lower risk to the urethra and bladder.

The helical passer can then be removed with a reverse rotation of the handle, and the plastic tube and tape can be pulled completely through the skin.

We repeat the technique on the other side, of course, and then ensure that the tape lies flat under the urethra without tension. I choose to set the tape using a "cough test." This has been shown to be superior to empiric or visual setting in a study by Dr. Miles Murphy and colleagues at the University of Louisville (Ky.).

Because the inside-out technique offers safety advantages over the outside-in technique, I believe we have an obligation to at least inform patients that the option exists, even if we're having success with the original retro-pubic TVT or the outside-in procedure.

We also can look forward to seeing yet another generation of synthetic midurethral slings in the coming year or so. The new sling can be placed in either a hammock or a "U" configuration with only a single incision in the anterior vaginal wall. An instrument deploys the tape by pushing it into position, rather than by pulling it into position as the TVT and obturator procedures do. There is no exit site, so even less tissue is traumatized.

We'll need to demonstrate durability and acquire more robust data, but the preliminary data look promising. ■