I n the Au-gust edition of Master Class, Dr. Mick ey Karram dis-cussed the use of tension-free vaginal tape (TVT) for the treatment of symptomatic stress urinary incontinence. Although both the success rate and subsequent patient sat-isfaction with TVT have proved to be ex-cellent, the risk of bladder perforation re-mains a concern. Because of this risk, I have continued to perform laparoscopic retro-pubic urethrolysis (Burch procedure) for se-vere stress urinary incontinence.

In this edition of Master Class, the sec-ond generation of midurethral slings—known as the transobturator tape (TOT) proce-dure—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 obstet-rics and gynecology at Northwestern University, Chicago. He is the director of Evanston Northwestern Healthcare’s di-vision 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. Lu-cente is a clinical professor of obstetrics and gynecology at Temple University in Philadelphia. He is the chief of gynecolo-gy at St. Luke’s Health Network in Allen-town, 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 Reconstruc-tive Surgery in Allentown, as well as chief of the Section of Female Pelvic Medicine and Reconstruc-tive Surgery at Abington (Pa.) Memorial Hospital.

Dr. Miller, a reproductive endocrinologist in private practice in Arlington Heights, Ill., and Naperville, Ill., is the medical editor of this column.

Synthetic Midurethral Slings and the Attractiveness of TOT

Dr. Emmanuel Delorme addressed the issue in 2001 by describing the first transob-turator tape (TOT) procedure. In this approach, the sling is placed transper-ineally beneath the ischiopubic rami, rather than retropubically. 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 retropubic space and instead insert the tape through a transobturator approach, we would have little or no chance of hitting the bladder or urethra—bladder perfora-tions have occurred in approximately 3% of TVT procedures, according to re-port—and we would alleviate the risk of bowel injury. Nor would we go near the abdominals. Routine cystoscopy, moreover, might be unnecessary.

Today, transobturator tape (TOT) proce-dures 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 tri-al comparing TVT and TOT in approximately 60 patients, Dr. Renaud de Tayrac demonstrated that at 1 year, similar num-bers of patients were cured and signifi-cantly improved (over 90%). Patients un-dergoing 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 pa-tients, that complication affected none of the TOT patients.

(Indeed, 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 urgency or frequency. It appears that TOT is less likely to impair bladder emptying, which, ironically, can be more problematic to patients than their original stress in-continence. The last thing we want to do is to alleviate the stress urinary inconti-nence only to induce or exacerbate any urge urinary incontinence.

There’s still a place for retropubic slings, however. Small trials have also shown that patients with intrinsic sphincter deficien-cy (ISD) have a higher success rate with the TVT procedure than with TOT, which makes sense when we consider the con-fi gurations of the two midurethral slings: the original retropubic sling’s U-shaped fit around the urethra, and the gentler ham-mocklike configuration of the transobtu-rator 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 H2O.

For most patients other than those with ISD, though, TOT now seems to be the preferable minimally invasive treatment. In addition to being safer and effective, it is easier to learn than the original TVT ap-proach, especially for physicians who are not yet comfortable or experienced with the retropubic 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 de-scribed by Dr. Delorme)—the transobtu-rator sling is placed inward through the labial fossae 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 de-cide 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 ap-proach, 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 post-operative urodynamic testing that was completed by about 66% of the patients, we found no significant difference in the percentage of patients cured of stress urin ary incontinence (97% TVT vs. 90% TOT). And based on results of postoperative quality-of-life questionnaires, we con-cluded that subjective cure rates were sim-ilar between the groups (87% TVT vs. 89% TOT).

TOT did, however, offer the advantage of...
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 exists through the incisions without any tension.

Some physicians use spacing devices, but I like to look at the mesh visually. If the mesh under 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.

The safety of this approach is ensured by finger-tip 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 pubis, 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 "tightly." 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 Lige (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 obturator foramen and can potentially disrupt that anterior branch. The hematoma 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 perineal dissection, we are minimizing the risk of urethral denervation.

The outside-in technique involves more perineal dissection: One simply must dissect more tissue to assure the palpation cues that the bladder is in place. Healing and re-eruption 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," that they may suffer an insult that could lead later to ISD. It is quite possible that we are eroding the urethral 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 innermost part of the obturator externus muscle. This will greatly 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 pass through the obturator membrane, at which point it is not longer advanced, but rather is simply rotated and swung into position, which allows it to curve around the bone and exit through the thigh.

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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 transpubic TVT or the outside-in procedure.

We also can look forward to seeing yet another generation of synthetic midurethral slings in the coming year. Now long can be placed in the incoming incision 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 and then carrying the tape to the other side, of course. 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.