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UROGYNECOLOGY

Tradition is yielding to new technology's advantages, time-tested though they are not—yet

Even as we scramble to gather definitive evidence on the immediate and long-term benefits of new technologies, they are supplanting tradition in the surgical treatment of incontinence and prolapse. Surgeons have been swift to adopt synthetic mesh and the new generation of needle suspension procedures, which offer the double advantage of a shorter operative time and shorter postoperative recovery. Yet, we lack well-designed randomized prospective clinical studies on whether outcomes and complication rates are better than traditional therapies such as vaginal colporrhaphy and paravaginal repair.

There hasn't been time.

These innovations came onto the market in rapid succession, accompanied by aggressive corporate promotion, physician interest, and, in turn, pressure from patients. Improved reimbursement for quicker, easier procedures also entices many physicians to become "early adopters." (Recent addition of the CPT code for mesh/graft use in prolapse surgery [CPT 57267], increases reimbursement over traditional procedures.)

It is important to keep a cautious but open mind. Given the blind needle techniques and use of biomaterial grafts and synthetic meshes, these procedures may not be for every surgeon or every patient. As always, astute clinical judgment and critical analysis of the data and anecdotal experience are recommended.

Transobturator sling

The needle-guided synthetic mesh midurethral sling was rapidly adopted as the treatment of choice for stress urinary incontinence due to urethral hypermobility and intrinsic sphincter deficiency, soon after it was described in 1995.¹

With the transvaginal tape (TVT) procedure, the learning curve was shorter and so were hospital stays and recovery, compared with abdominal Burch colposuspension and traditional bladder neck slings. Furthermore, cost efficiency improved,² and the persistent cure rate was 85% from 2 to 8 years.³

However, needle passage through the retropubic space can cause vascular, bowel, or bladder injury, even in the hands of experienced surgeons. An August 2005 French survey⁴ of 92 surgeons who performed 12,280 TVT procedures reported these complications: perioperative bladder injuries, 901 (7.34%); cases of complete postoperative urinary retention requiring catheterization, 809 (6.59%); vaginal mesh exposure, 26 (0.21%); retropubic or vulvovaginal hematoma, 39 (0.32%); and major organ injuries, 10 (0.08%).

The transobturator (TOT) approach, introduced in 2003,⁵ is simpler, with fewer complications. The sling is placed in a similar manner in the midurethral position, but the insertion points overlie the obturator space in the genitofemoral crease lateral to the vagina. A needle pass-

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ing through the obturator membrane exits the vaginal incision without entering the retropubic space, theoretically averting risk of bowel, bladder, and major blood vessel injury.

Although the TOT is thought to be safer in this regard, complications including urinary retention, obturator hematoma and nerve injury, and urethral injury/erosion have been reported.⁶

A variety of TOT sling kits are available, none with proven superiority.

In a recent randomized, prospective trial in which 61 women had TVT or TOT, there were no bladder injuries in the TOT group, and 9.7% (n=3) in the TVT group ($P>.05$). The postoperative urinary retention rate was 25.8% (n=8) in the TVT group and 13.3% (n=4) in the TOT group ($P>.05$). Cure rates (83.9% vs 90%), improvement (9.7% vs 3.3%), and failure (6.5% vs 6.7%) were similar.⁷

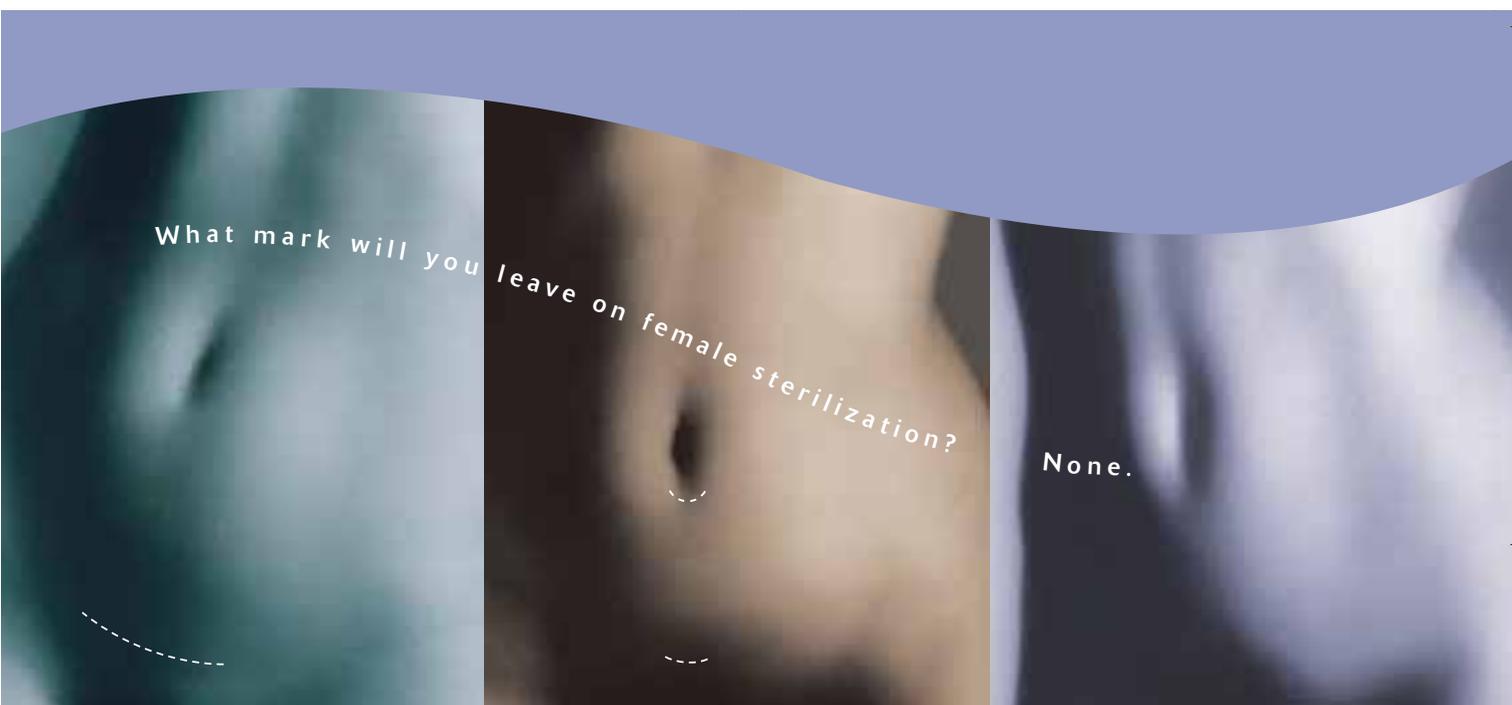
The transobturator suburethral sling is encouraging, although it is unclear

whether it is effective in patients with intrinsic sphincter deficiency, especially with a fixed or lead-pipe urethra. We need studies to determine how to match the right procedure to the right patient.

Which sling for which patients?

My indications for TOT vs. TVT, which are based on personal experience and available data, may change as data accumulate (**TABLE**). Indications are often surgeon-specific, depending on clinical experience.

In our review of 210 TOT slings over a 16-month period at 2 centers, we found a cure rate of 88% and an improvement rate of 1.9%. The complication rate was 24%; intraoperative and postoperative complications were all minor and mostly self-limited⁸: 1 cystotomy, 1 urethral injury, 2 hematomas, 1 erosion, 16 complaints of transient groin pain, 5 cases of urinary retention requiring reoperation, and 23 cases of de novo urge incontinence.



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leave on female sterilization?
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essure[®]
The alternative to incision

■ Adjustable suburethral sling

One of the challenges in placing a suburethral sling is adjustment for efficacy without overcorrection and resultant bladder neck obstruction, urinary retention, or persistent and refractory overactive bladder symptoms. An adjustable transvaginal midurethral synthetic sling procedure was recently introduced in the United States: the Remeex Tensionfree Readjustable Tape, (*Neomedic International, Spain*). A retro-pubic minimally invasive midurethral sling is attached to sutures that are taken through a tensioning device placed above the fascia in the suprapubic region. The tensioning device has a small adjustment kit similar to a screwdriver, which is left in place at the time of surgery. The sling is intentionally left loose for postoperative adjustment. Following surgery, a filling cystometrogram confirms stress incontinence. The sling is then progressively tightened until the leaking ceases. This technology is designed to prevent or correct overtightening, and avert bladder outlet obstruction. The sling can be adjusted via a small suprapubic incision, even years later; adjustment has been reported up to 7 years later.

In a recent study of 62 patients with stress urinary incontinence, 58 patients (94%) were completely dry and cured, and 4 patients (6%) reported occasional slight urine leakage. Operative time was 20 to 40 minutes (only stress urinary incontinence and cystocele). Six patients required long-term readjustment (5 to increase tension and 1 to reduce tension). No major intraoperative complications occurred. Late complications included suprapubic wound pain (12 transitional and relieved with analgesics), 3 urinary tract infections, 2 wound seromas, 1 case requiring prosthesis removal due to infection, and 3 cases of hyperactivity *de novo*, which required anticholinergic treatment.⁹

Although postoperative urinary retention or postoperative failure is relatively uncommon in transvaginal or transobturator suburethral sling procedures performed by experienced surgeons, the adjustable sling may be especially useful in patients

with increased risk of postoperative voiding dysfunction, as well as limited urethral hypermobility/fixed urethra, because the sling can be adjusted long after the operation. Risks include infection due to foreign body (indwelling placement of the tensioning device) as well as palpation and incisional discomfort in very thin patients. Further clinical experience is needed, but the concept of a sling that can be adjusted immediately or even years later is appealing.

■ Graft/mesh augmentation for prolapse repair

Augmentation of pelvic prolapse repair using mesh and graft materials is used increasingly in an effort to improve long-term outcomes, although we lack randomized prospective data and long-term outcome studies. Synthetic materials offer ready availability, consistent tissue properties, cost effectiveness, and permanent placement, although there are risks: infection, dyspareunia, and erosion or exposure. Success and complications may depend on surgical technique, choice of material, patient selection, postoperative management, or other factors.

The overall success rate was 94% at a mean of 17 months after operation, in a study of 63 women in whom polypropylene mesh was used for augmentation of cystocele and rectocele. However, the authors recommended abandonment of the procedure due to an unacceptably high rate of complications.¹⁰ In the 32 women undergoing anterior repair, sexual activity rate did not alter, but dyspareunia increased in 20%. Urge and stress incontinence did not change, but urgency improved in 10%; 13% had vaginal erosion of the mesh. Of the 31 patients undergoing posterior repair, sexual activity decreased by 12% and dyspareunia increased in 63%. Constipation improved in 15% and anal incontinence in 4%; 6.5% had vaginal erosion of mesh and 1 required mesh removal for abscess.

In another study, results were improved and complications were fewer.

FAST TRACK

The adjustable sling may be especially useful in patients at risk of postoperative voiding dysfunction

TABLE

Transvaginal vs transobturator sling

INDICATIONS	ADVANTAGES
Transvaginal (retropubic) Physically active patient Thin, young patient Limited urethral hypermobility/ internal sphincter dysfunction	Avoids groin discomfort with activity Long term data available Data supports use/ dynamic backboard
Transobturator Elderly patient Significant overactive bladder/ urge incontinence Previous retropubic surgery Obesity Inexperience with TVT	Less postop voiding dysfunction Less urethral obstruction Less risk of retropubic complication Less risk of needle-passage complication Less risk of periop complications

After 2 years, 24 of 26 women who had posterior repair with polypropylene mesh were cured (92.3%) and 1 had asymptomatic stage 2 rectocele. All but 1 reported improved symptoms and quality of life. No postop infection or rectovaginal fistula was reported; there were 3 vaginal erosions (12%), and 2 patients had de novo dyspareunia (7.7%).¹¹

To make graft/mesh augmentation easier and faster, needle-suspension techniques were recently introduced. Needles are inserted either through the transobturator space (anterior mesh placement) or ischioanal fascia (posterior placement) and exit through the pelvic sidewall in proximity to the ischial spine. A multi-arm mesh is then attached to the needles, which are withdrawn. Tension secures the mesh and provides “tension-free” anterior or posterior wall support. Colporrhaphy can be performed prior to mesh placement at the surgeon’s discretion.

Because we have few data on patient selection or long-term safety and efficacy (most of it presented at recent meetings^{12,13}), these techniques call for caution. Blind needle passage can be associated with complications such as rectal injury and rectovaginal fistula.¹⁴ But complication rates may reflect early evolution and may improve with time and experience. ■

FAST TRACK

Complication rates may reflect early evolution, and may improve with time and experience

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