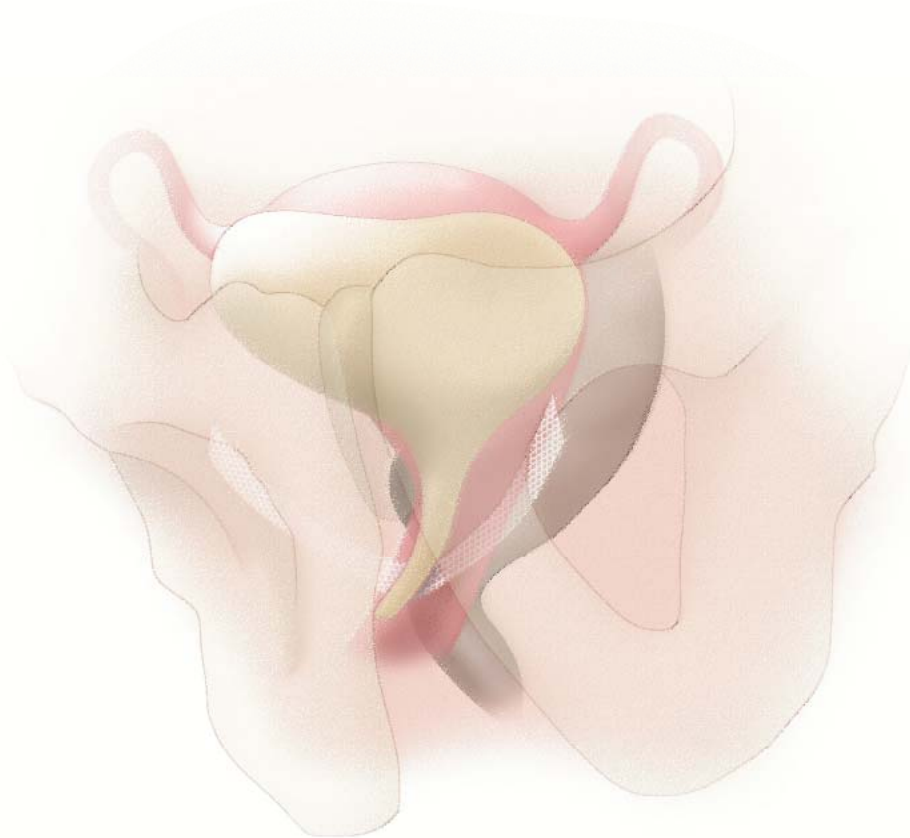


Transobturator Sling for Stress Incontinence (Subfascial Hammock)



Introduction/Background

As stated by the American Urologic Association consensus statement in 2001, there are only 2 procedures that are proven to have effective long-term cure rates for the treatment of stress urinary incontinence (SUI). These procedures are the abdominal Burch Colposuspension (or MMK) and the sling procedure that is completed vaginally. However, in the past, the sling procedure was far from standardized. There have been multiple different descriptions using different materials for the sling (fascia from the patient, cadaveric fascia or dermis from humans or animals, synthetics, etc), different anchoring points, and different methods to adjust the tension of the sling. In many cases patients had to undergo general anesthesia, were in the hospital for several days, required a catheter to drain the bladder coming out of the abdomen (because it took so long to void on their own) and many patients suffered high rates of voiding dysfunction following these slings.

However the introduction of the tension-free vaginal tape procedures to the United States in the late 90's revolutionized the treatment of SUI. It introduced a standardized sling procedure that could be completed safely in 20 minutes under local anesthesia, utilizing 3 very small incisions with minimal dissection, a cough test for individual tension patient adjustment and excellent cure rates. Over 500,000 of these procedures have been completed worldwide.

What does 'tension-free' mean?

Tension-free slings are used to treat stress urinary incontinence caused by urethral hypermobility and intrinsic sphincter deficiency. In this approach, a synthetic transvaginal suburethral sling is placed through the retropubic space without using suspension sutures. The sling is held in place by the friction between the mesh and the tissue canals created by the metallic needle passers. Scar tissue later fixes the mesh, preventing migration.

Because the sling is not anchored to the pubic bone, ligaments, or rectus fascia, it is considered "free of tension." The result is a midcomplex urethral support that limits urethral descent, improves the stabilization mechanism generated by pubourethral ligaments and levator ani muscles, and reinforces support of the backboard vaginal hammock.

Transobturator Sling- New, Safer Approach

Despite its relative safety, the tension free vaginal tape procedures require the blind passage of needles through 2 small incisions in the abdomen just above the pubic bone. The retropubic space that the needle has to pass through to get to these abdominal incisions is also a very vascular space with venous plexuses and the potential for injury to large blood vessels in the pelvis. Secondary to this and the areas that the needle has to pass to place the mesh tape, there is potential for complications such as injury to the bladder, intestines, or nerves in the pelvis and/or abdomen. All of these injuries have been reported in the literature. Secondary to this, physicians in Europe began investigating to find a safer approach to place the mesh tape sling.

Risks of Retropubic Needle Passage

- Bladder injury**
- Bowel injury**
- Major vascular injury**
- Nerve injury**

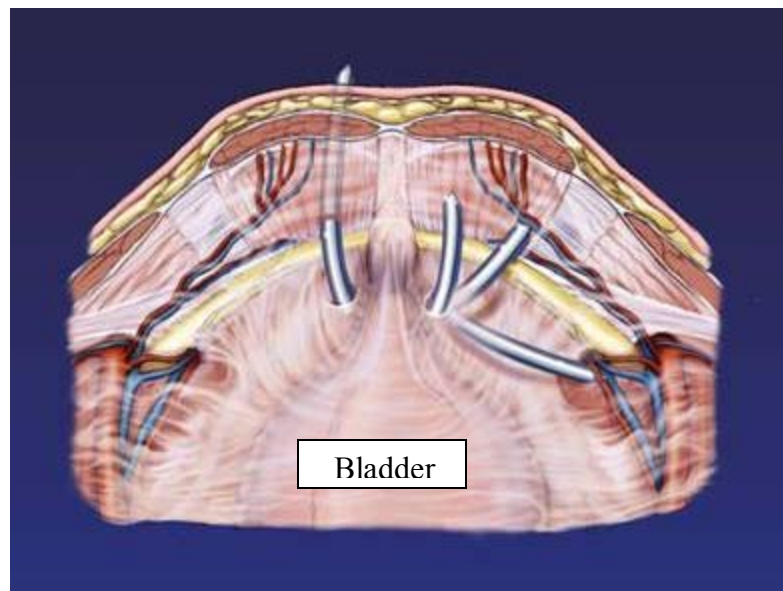


Figure 1. *Passage of Retropubic Needles for TVT, SPARC, etc.*

The needle on the left shows a safe passage, the needle on the right shows potential injury to abdominal wall vessels or pelvic vessels or nerve.

The Transobturator Sling

In the Netherlands in 1998, Nickel et al reported a successful sling procedure using a polyester ribbon passed through the obturator foramen and around the urethra for treatment of refractory urethral sphincter incompetence in female dogs. In France in 2001, Delorme introduced the transobturator sling procedure in humans. Dargent et al then performed the operation in 71 patients using a technique inspired by Delorme, and found the short-term results similar to those of the TVT. Thousands of procedures have been performed in Europe and more recently in the United States. Dr. Moore and Miklos were two of the first surgeon's in the United States to utilize this newer, safer approach to the tension free tape sling procedure. They both have traveled to France to operate and train with the experts and world leaders to bring this technology to the US.

Advantages of Transobturator Approach

- Safer, faster, more efficient**
- Decreased risk of:**
 - Bowel Injury**
 - Bladder Injury**
 - Major Bleeding**
- No Retropubic Needle Passage**
- No Abdominal Incisions**
- More Anatomic Position of Tape**

Very small incisions are placed in the groins (one on each side) and the same small incision is made in the vagina under the urethra, allowing the mesh tape to be placed under the urethra in the correct position without having to pass needles blindly through the retropubic space and the abdominal wall. The space that the needle passes through has been extensively studied (Dr Moore and Miklos have done numerous cadaveric dissections to study the anatomy of the space) and has been found to be a very safe space to work in. There is essentially NO risk of major bleeding (no major blood vessels), bowel, bladder or nerve injury. Many physicians are concerned of the route of the obturator nerve, however we have completed dissections showing that if done correctly, the obturator nerve is nowhere near the surgical tract of the needle (see anatomy below). The needle is also guided by a finger placed vaginally throughout its tract, therefore there is minimal blind passage of the needle.

The transobturator sling is subfascial, ie the needle or the sling NEVER enters the retropubic space

Position of Mesh

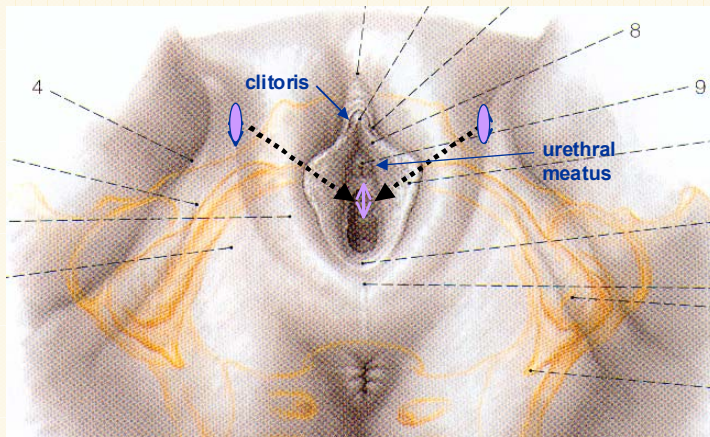
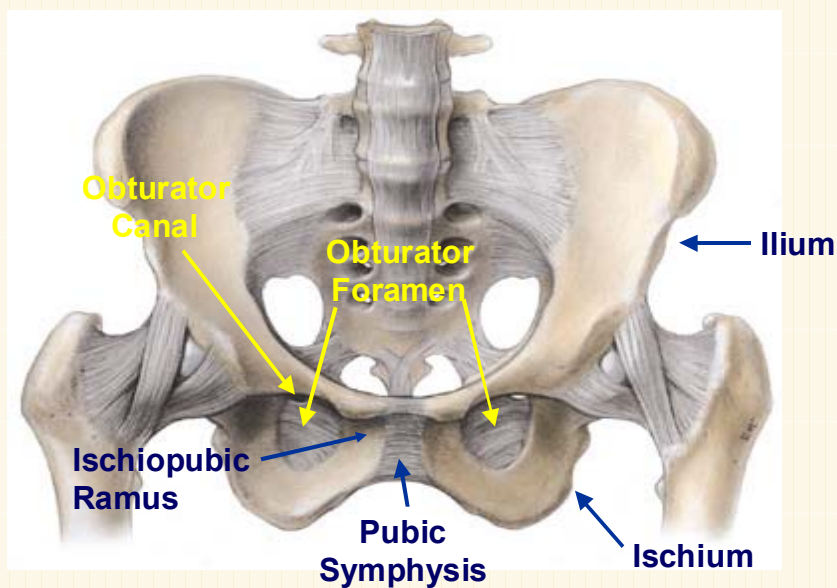


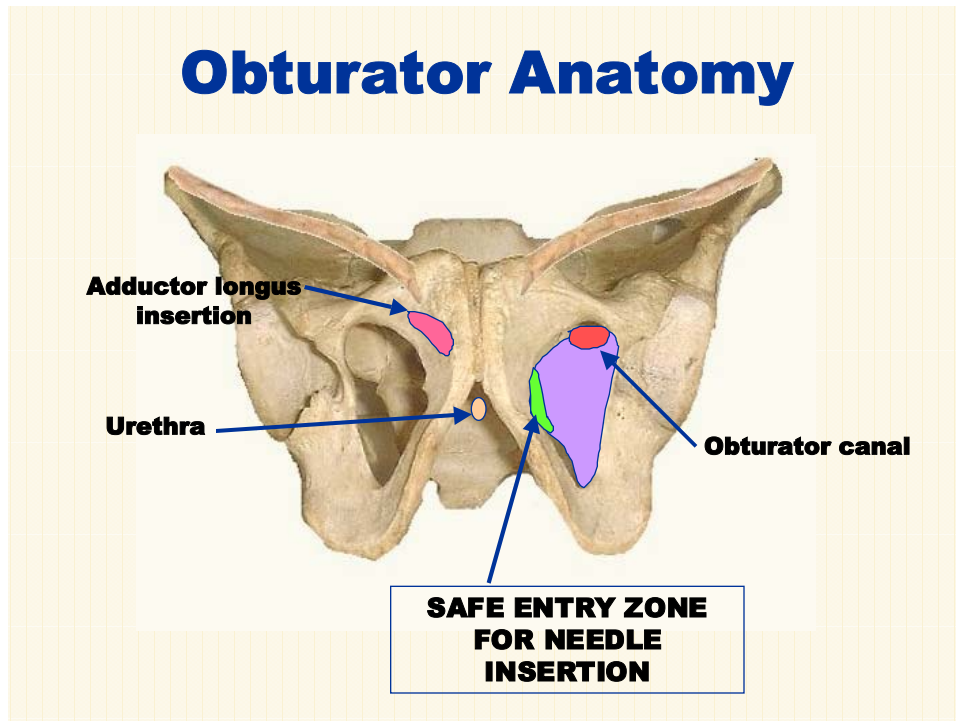
Figure: The dotted arrows show the final position of the transobturator sling placement. The blue circles in the groin are where the small stab incisions are made to place the polypropylene mesh tape sling.

Transobturator Anatomy

Obturator Anatomy



The obturator foramen is covered by a thick membrane called the obturator membrane. The external and internal obturator muscles cover this membrane. It is a very safe space anatomically, ie there are no major vascular or nerve structures near the ischiopubic ramus. This is the area that the needle is passed for the sling placement. As can be visualized by the drawing, the obturator canal is very lateral and superior to the ischiopubic ramus, this is the area that the obturator nerve and vessels transverse.



The needle to place the TOT sling is passed through the groin incision, the obturator membrane and around the descending ischiopubic ramus (the area marked in green in the above diagram). A small incision is made vaginally as well and the needle is guided throughout its course with a finger placed in the vaginal incision, thus protecting the urethra and making it safer than just a “blind” needle passage. The mesh tape (the same mesh tape that is used for SPARC, TVT etc) is then attached to the needle and brought back through the incision (see surgical technique below). The obturator vessels and nerve coming through the canal (in pink above) are far away from the surgical field, thus making injury very unlikely.

The TOT needle used to place the sling has minimal blind passage making it very safe, additionally NEITHER the needle nor the sling has to be passed through the abdominal wall like traditional slings

TOT Needle Passage

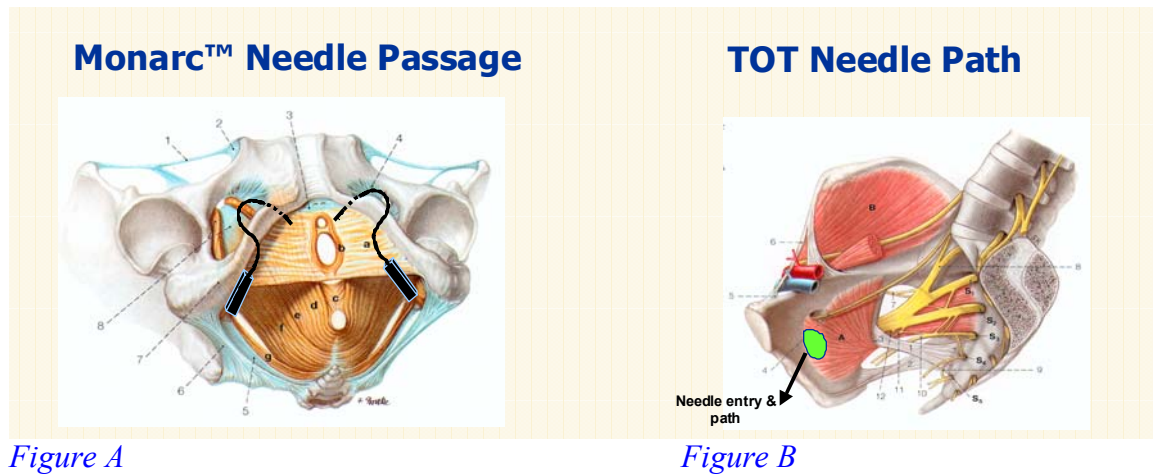


Figure A demonstrates the positioning of the needle passage in the Monarc transobturator sling, made by American Medical Systems. This is just one of the types of TOT slings currently on the market.

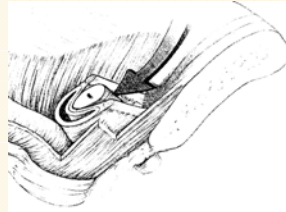
Figure B demonstrates the passage of the needle viewed from the inside of the pelvis. Again a very safe area to pass the needle through to place the sling. This area is below the fascia of the bladder and therefore the retropubic space is never entered and the bladder remains very protected with this approach.

TOT Mimics Normal Anatomy

The transobturator sling forms a subfascial hammock of support under the urethra. This mimics the normal position of the pubourethral ligament. This is the ligament that typically provides the backboard of support to help prevent urinary leakage with stress events such as coughing, laughing, sneezing, exercising, etc. When this ligament is damaged or stretched out secondary to childbirth, aging, chronic straining, etc, stress urinary leakage may ensue. The position of the transobturator sling reproduces the natural position of this ligament and in a sense replaces the damaged ligament with a permanent mesh tape that provides the support needed to prevent leakage (**figure C** below). As can be seen in **figure D** below, the angle of the TOT sling is much less acute than the traditional pubovaginal sling procedures such as the TVT or SPARC, therefore not only is this more anatomic and natural, it also makes sense that there is less problems with urinary dysfunction such as urinary obstruction (not being able to void). **Figure E** is an MRI that demonstrates the position of the TOT sling is almost identical to the natural position of the pubourethral ligament.

Subfascial Hammock Mimics Pubourethral Ligament

Monarc™ Subfascial Hammock mimics normal anatomy



Normal pubourethral ligament support - DeLancey

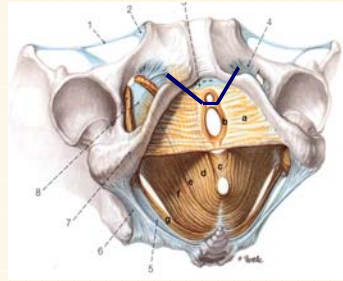
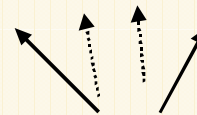


Figure C: Position of TOT sling duplicates position of pubourethral ligaments

TOT Subfascial Hammock vs. Pubovaginal Sling

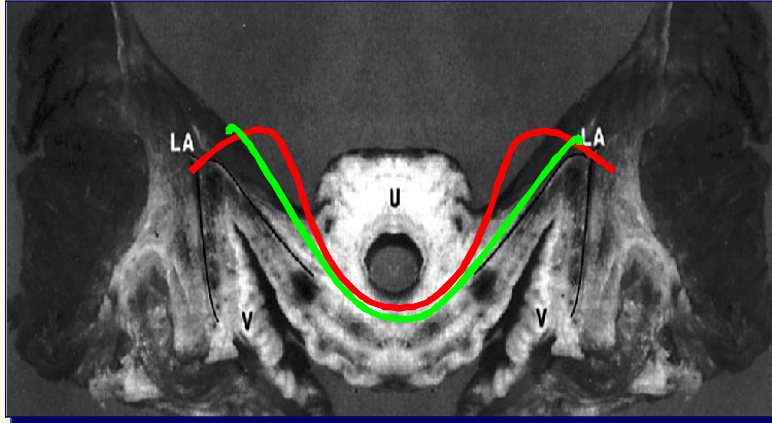
PV Sling (dotted)



Transobturator (solid)

Figure D: TOT sling angle is much less acute than traditional sling, it is felt that this angle is more natural and may reduce post-op voiding dysfunction.

Monarc™ & Normal PU Ligament



LA = Levator Ani U = Urethra V = Vagina

Figure E: The TOT sling (red) is shown in this MRI to mimic the natural position of the pubourethral ligament (green) which is the ligament known to be responsible for maintaining continence.

Clinical Results and Complications

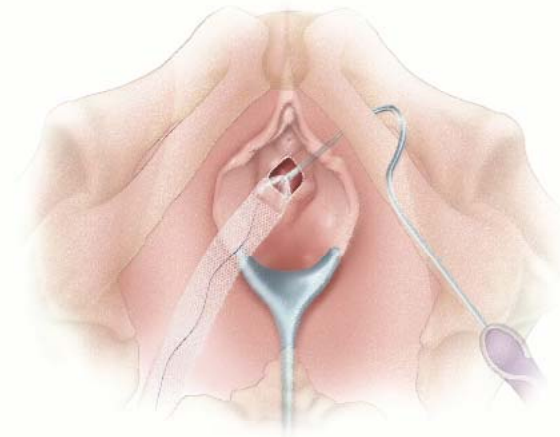
The transobturator sling procedure was originally described in the Netherlands in 1998 and since then there have been thousands of TOT procedures completed in Europe. In France in 2001, Delorme introduced the transobturator sling procedure in humans. Dargent et al then performed the operation in 71 patients using a technique inspired by Delorme, and found the short-term results similar to those of the TVT. Professor Georges Mellier (one of the world leaders in the procedure) from France recently reported his data on the procedure at the 2003 International Urogyn Meeting in Buenos Aires. He presented over 100 patients that had TVT's and 100 patients that had TOT's, the cure rates and complication rates were comparable at 1 year (link to IUGA 2003).

The procedure was introduced in the United States in the spring of 2003, since that time there have been over a 1000 procedures done in the US, with no major complications reported and short term results comparable to that of retropubic tension-free sling procedures (ie TVT, SPARC, UROTEK, etc).

Risks and complications are rare, however include the same risks associated with any tension-free mesh sling including bleeding, infection, voiding dysfunction, urinary retention, mesh erosion (in the vagina or urethra), pain in the vagina or groins. The risk of

bowel or bladder injury as well as the risk of major bleeding are significantly reduced compared to retropubic approaches.

Atlanta Urogynecology Experience

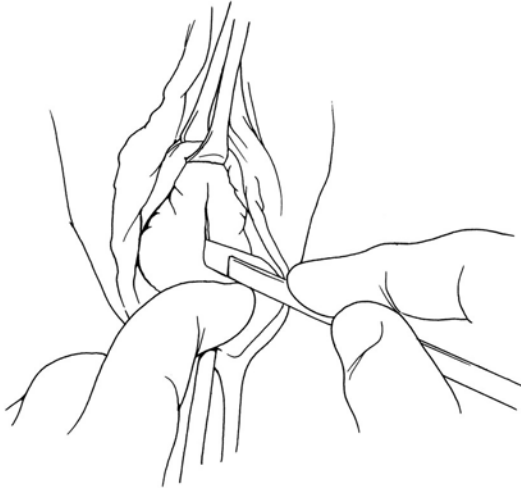


Dr Moore and Miklos were two of the first surgeons to bring this new technology to the United States. They are leaders in the Southeast and the US in both performing and teaching the procedure. Both surgeons took several trips to Europe and France to learn the procedure and operate with the experts who developed the technique. Dr Moore has traveled throughout the country and has taught surgeons in Dallas, Phoenix, Miami, Raleigh, NC, Sacramento, Ca, Las Vegas and Seattle. He was also invited to lecture on the topic to world leaders at the International Urogyn Mtg in Buenos Aires Argentina. Surgeons from all over the country also travel to Atlanta to learn the new technique from Dr Miklos and Moore.

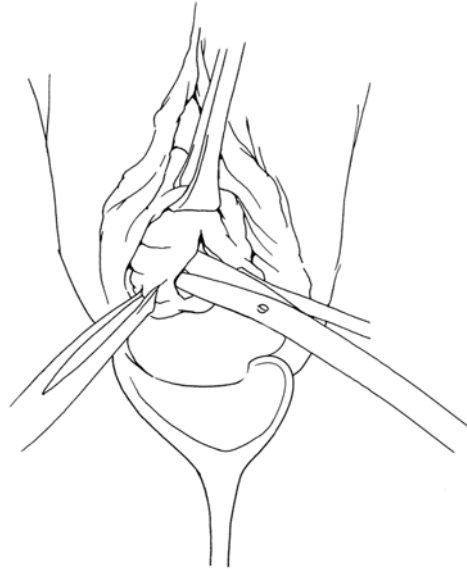
The TOT procedure takes as little as 10 minutes to perform and can be completed under local anesthesia with minimal risks

To date Dr Miklos and Moore have seen the same excellent short term clinical success that the Europeans have experienced. No patients have complained of postoperative pain in the area of the adductor muscles of the thigh, and no sling erosions have occurred. No patients have had any significant bleeding or other major complications. The procedure takes less than 10 minutes to perform and can be completed under local or regional anesthesia. They also have found this approach useful in obese patients and women with retropubic scarring, in whom retropubic needle passage can be a challenge. They also believe that by keeping the sling sub-fascial and away from the bladder and the retropubic space, that they also may be reducing the risk of creating bladder irritability that may occur with slings that are in contact with the bladder wall.

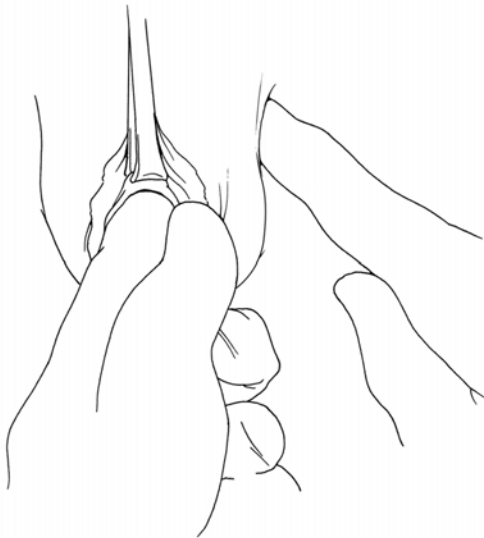
Surgical Synopsis-TOT Sling



Step 1. Small incision is made under the urethra



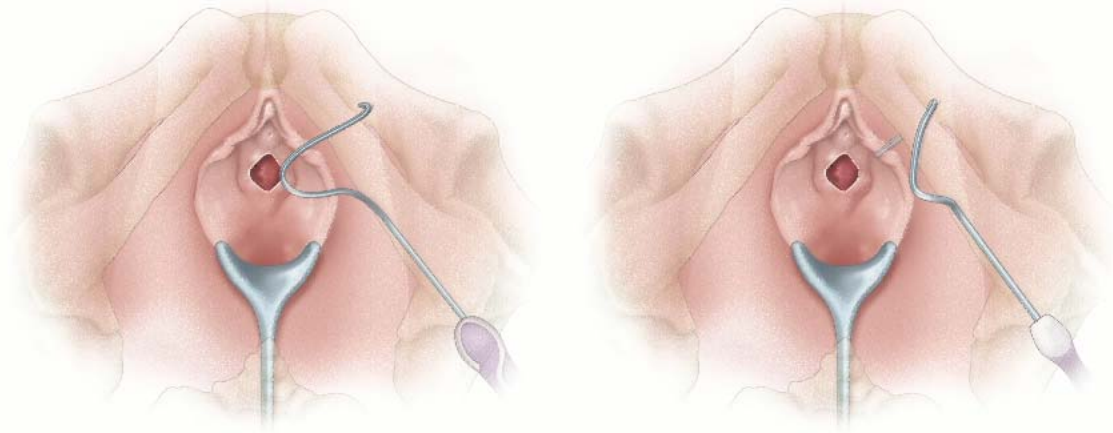
Step 2. Vaginal epithelium is dissected free



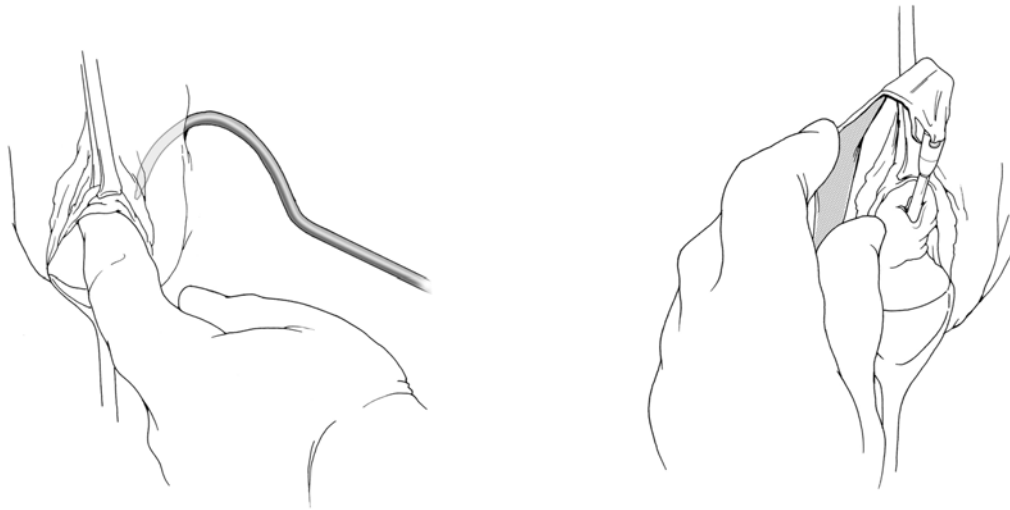
Step 3. Area of groin incision located 1cm inferior to adductor longus tendinous insertion (level of clitoris)



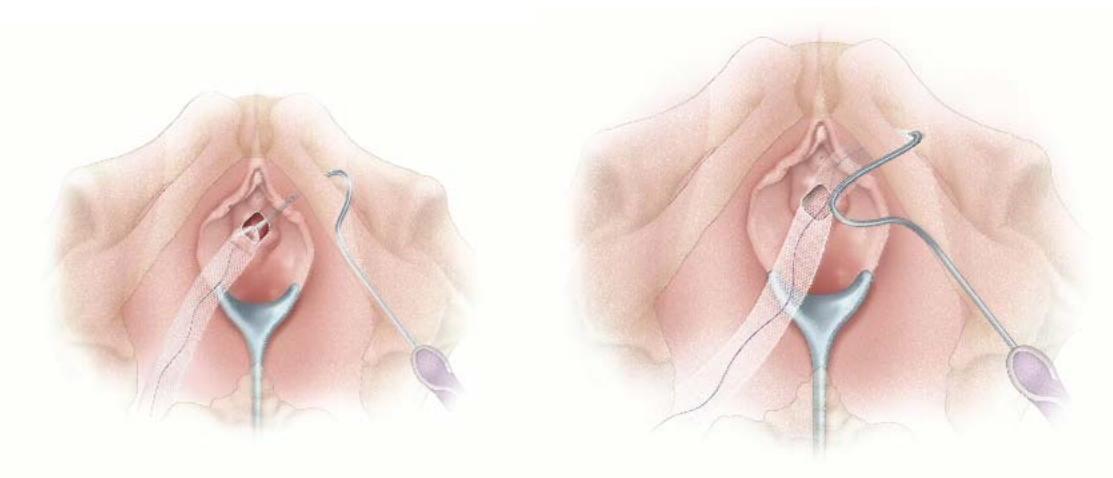
Step 4. Finger placed in vaginal incision to guide needle. Needle placed in groin incision and passed



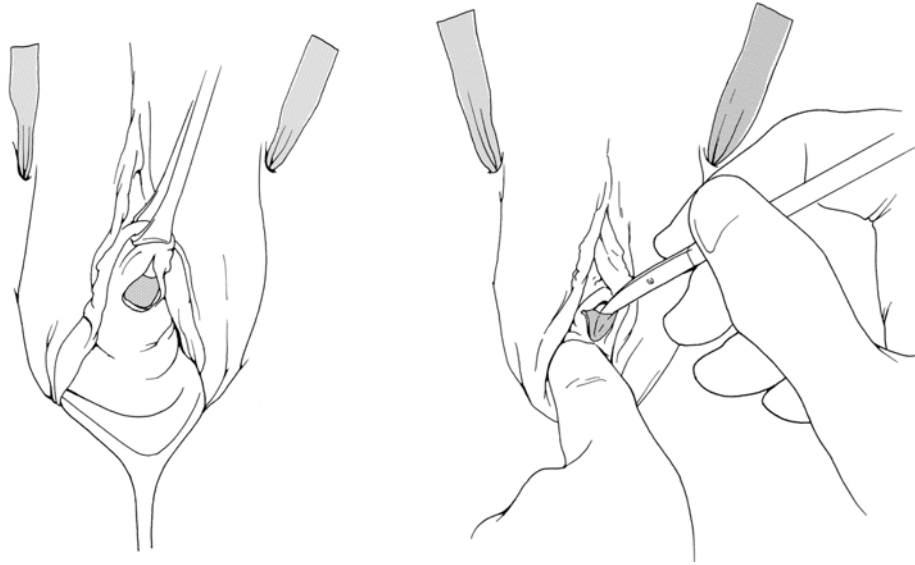
Step 4 cont'd. The needle is passed through the groin incision, through the obturator membrane and muscles and brought into the vaginal incision.



Step 5. The needle is brought through the vaginal incision and the tape is attached to the needle with the connector.



Step 6. Connected tape is then brought back through the groin incision



Step 7. Needle and tape is passed on the opposite side. Tape is then adjusted with an intra-operative cough test and adjusted until no leakage occurs. Excess mesh is cut off at the groin incisions and these are closed with steri-strips and vaginal incision is closed with absorbable suture.

