EXPERT REVIEWS

Minimally invasive treatment for female stress urinary incontinence

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Advances in synthetic slings using a variety of surgical approaches during the last decade have left surgeons confused as to which procedure may be the most beneficial for the incontinent female. Using PubMed, MEDLINE and manual searches, we reviewed bibliographic databases from 1995 to the present day focusing on the treatment of female stress urinary incontinence (SUI) by synthetic slings. A total of 69 articles were reviewed that discussed a variety of surgical approaches, efficacy and complications involved with treating SUI via synthetic slings. It was observed that there were three overlapping eras of synthetic sling treatments based on the type of surgical approach utilized, retropubic, transobturator and single incision. Each advancement during the last decade has attempted to address complications observed in earlier treatment options. Some have introduced unexpected and unforeseen consequences, such as unwanted tissue perforations in the retropubic approach, occasional groin pain in the transobturator approach and unknown long-term efficacy (due to its most recent market introduction) with the latest single-incision slings. We conclude that the surgical treatment options for female SUI using synthetic slings have changed dramatically in the last 10 years. The search for improved treatments with shorter surgical time, decreased patient complications and long-term efficacy will continue.

KEYWORDS: mini-sling • pubovaginal • retropubic • stress urinary incontinence • suburethral • SUI • synthetic sling • transobturator

The standardization subcommittee of the International Continence Society defines female stress urinary incontinence (SUI) as the complaint of involuntary leakage on effort or exertion, or on sneezing or coughing [1]. Urinary incontinence appears to affect at least a quarter of women between the ages of 30 and 60 years of age. Hampel *et al.* have reported on objective data in several studies involving middle-aged women with a prevalence of incontinence at 29 ± 9.9%. In other studies reviewed, there is a prevalence with greater variability, ranging from 14 to 41% with a mean of 24.5% [2]. In addition, it is generally assumed that incontinence is under-reported in some segments of the population, especially among the elderly.

During the last 10 years, there has been a steady progression and evolution of pubovaginal slings used in treatment of SUI. The landmark article by Ulmsten and Petros in 1995 describing the intravaginal slingplasty [3], a minimally invasive ambulatory surgical treatment for female SUI providing successful outcomes and minimal complications, hailed a new era for patients, physicians and medical device companies worldwide. The sling was developed based on the landmark hypothesis of the integral theory of Petros and Ulmsten, that a weak pubourethral ligament inactivated the three muscle forces that activate the urethral and bladder neck closure mechanisms that create continence [4]. They then demonstrated that a lax ligament cannot be tightened by suturing and it was proven on experimental animals that a tape implanted at midurethra could create an artificial collagenous neoligament by using the foreign body reaction in a positive way [5]. By not suturing the tapes to the anterior abdominal wall, post-operative retention and urethral transection complications were prevented, and this helped convert the procedure to a day-care operation [6]. Ultimately, the intravaginal slingplasty has become better known by the descriptive term of the tension-free vaginal tape (TVT)

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sling and was trademarked with the commercial name of the TVT sling by Gynecare (Johnson & Johnson, NJ, USA), which was the first commercially available version of Ulmsten and Petros's original work. The evolution of modern pubovaginal slings and improved understanding of synthetic sling materials has been a primary focus in this field of treatment. This paper reviews the use of minimally invasive synthetic slings for SUI over the last decade, including the retropubic (RP), transobturator (TO) and single-incision approaches.

History of SUI surgical treatments

Over the past few decades, various surgical procedures and techniques have been available for treatment of SUI. Early Burch urethropexy and the Marshall–Marchetti Krantz (MMK) procedures were suprapubic approaches used to elevate paraurethral tissues to the Coopers Ligament or the pubic periosteum. The RP Burch urethropexy (i.e., Burch or MMK) and the pubovaginal sling have been recognized in the literature as the two leading and most effective treatment options for SUI (Figure 1) [7]. The Burch procedure, which involves elevating the bladder neck, has been called the 'gold standard', with subjective cure rates in the range of 82–95% at 1 year [8]. However, many physicians were interested in improving such outcomes while minimizing operative time and decreasing morbidity caused by these more invasive procedures.

In the 1990s, Ulmsten and his Scandinavian group developed the use of polypropylene tape as a suburethral sling for the treatment of SUI [9]. This early tension-free vaginal tape ultimately became known as TVT and revolutionized the treatment for SUI. The TVT tape was anatomically situated at mid-urethra rather than at the bladder neck, the latter being the location for most of the earlier treatment options. By placing the TVT mid-urethrally, Ulmsten targeted the area of the pubourethral ligament to restore continence. The pubourethral ligament is the effective anchoring point for the three muscle forces that affect the urethral (distal) and bladder neck (proximal) closure mechanisms, which create continence. This was demonstrated with video ultrasound in 1999, which also showed that midurethral pressure of the tape restored geometry and continence [10]. The result of the positioning of the tape was a restoration of urethral support and a correction of the patient's symptoms of SUI.

Placement of the TVT sling in most cases could be achieved under local, spinal or epidural anesthesia, which gave surgeons the option to conduct an intra-operative cough test, allowing them to evaluate the tightness of the sling and perform immediate adjustment if indicated. Patients typically were discharged after only a few hours from an ambulatory surgical center setting and reported faster recovery and fewer complications [11].

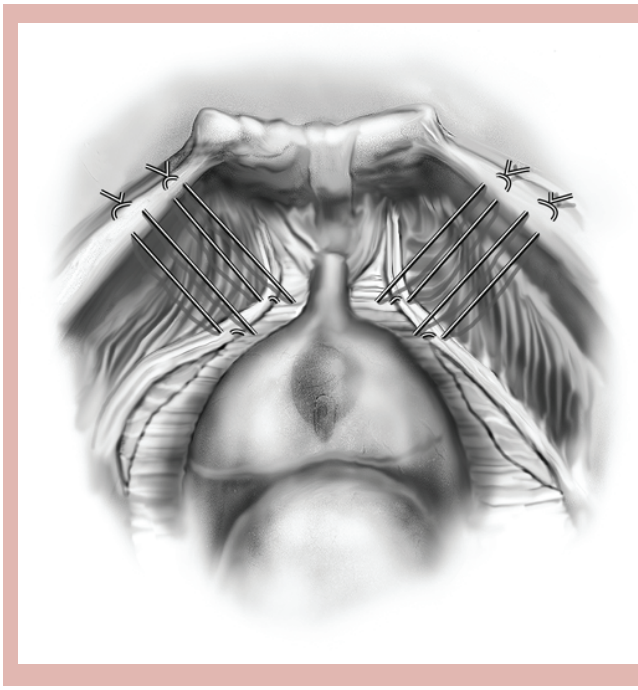

Figure 1. Burch Urethropexy supporting the vagina/pubocervical fascia proximal to the urethra.
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Material improvements

Early pubovaginal surgical approaches used a variety of sling materials, which ranged from autologous, allograft, xenograft or synthetic. Each type of material used for suburethral placement had its proponents and supporters; however, many modern day sling users have moved to the concept of tension-free, mid-urethral synthetic slings. In addition to Ulmsten, others have demonstrated that polypropylene materials are as efficacious and durable as a suburethral tape [12,13]. Subsequent to this early adoption of polypropylene as a safe, biocompatible material many synthetic slings have been introduced for use in RP, TO and the 'mini' sling applications.

Corcos and Feifer identified three separate categories of modern synthetic mesh based on materials and manufacturing methods: monofilament-knitted polypropylene, polyfilament-knitted polypropylene and thermally annealed polypropylene [14].

In addition, surgeons have learned the importance of pore size in synthetic mesh for tissue healing impact and the risks of tissue erosion or extrusion. The use of mesh material with a microporous structure has been postulated to be linked to numerous infectious events reported in the literature [15]. To promote tissue healing and the unobstructed infiltration of fibroblasts, a minimum pore diameter of 50 µm appears to be necessary [16]. Amid proposed a mesh material classification system that is based on pore size (Table 1) [17].

Two large commercial suppliers of sling material are Ethicon® (Gynecare) and American Medical Systems (AMS; MN, USA). Other suppliers include, Boston Scientific, Bard and Coloplast (Mentor). The majority of sling products on the market today, including all Ethicon (TVT, TVT-obturator [TVT-O],

Table 1. Mesh material classification system.

Class	Specifications	Available material
I	Macroporous (>75 µm); MA, PMN, FB infiltration; monofilament	Marlex and prolene
II	Microporous (<10 µm); no MA, PMN, FB; monofilament	Goretex, PTFE
III	Macroporous (>75 µm) + PMN, MA, FB; polyfilament	Mersilene, Teflon®
IV	Nonporous (<1 µm); no MA, PMN, FB	Silastic

FB: Fibroblast; MA: Mononuclear phagocyte; PMN: Polymorphonuclear neutrophil; PTFE: Polytetrafluoroethylene.

TVT-Secur™ [TVT-S]) and AMS products (SPARC™, Monarc™ and MiniArc™) use synthetic mesh, which is a monofilament-knitted polypropylene material (i.e., type I mesh). Earlier Mentor/Coloplast products (ObTape™ and Uratape®) utilized the thermally annealed, nonknitted, noninterwoven and nonelastic polypropylene (Corcos and Feifer's third category). Mesh modifications in these products caused a minor change in pore size that may have made capillary penetration more difficult, leading to possible greater rates of mesh extrusion [14]. In one study of 65 subjects who underwent SUI procedures using Uratape/Obtape slings, a 13.8% rate of tape extrusion was reported [18]. Both Mentor products have since been removed from the market.

Review of modern day minimally invasive slings

The TVT sling: the beginning of modern day RP slings

The initial RP sling to be introduced was tension-free vaginal tape or Gynecare TVT in 1996 (Figure 2). In the TVT procedure, trochars are introduced vaginally and are directed behind the pubic bone and exit suprapubically (a 'bottom-up' procedure). This procedure is performed in an outpatient setting under local anesthesia.

While the utilization of this procedure has grown since its introduction, there continues to be associated surgical complications including urinary retention, pain and *de novo* urge symptoms, as well as other rare but potentially serious injuries to the urethra, bladder, bowel, major vessels or nerves secondary to blind needle passage through the RP space. As discussed by Ward and Hilton, life-threatening complications from TVT occur rarely (0.009–0.04%) and include both bowel and vascular injuries [19]. Mortalities from TVT have also been observed with six of the eight reported deaths in their article attributed to bowel perforation [19].

In an effort to reduce the risk of bladder, vascular and bowel perforation complications, RP slings that used an abdominal-to-vaginal ('top-down') needle approach were developed with one such product being SPARC (Figure 3). In addition to the changed route of delivery, the size of the needles was smaller in diameter. Surgeons, particularly urologists, may have been more comfortable passing needles in a top-down approach, such as from the suprapubic region on the abdomen down to a finger placed in a vaginal incision, due to their experience with earlier procedures (i.e., Stamey or Raz needle suspensions or traditional pubovaginal slings). Additionally, the 'safety zone' in the RP space (Figure 4), which avoids the major vessels, has been discussed [20], and it may be easier to stay in this zone to avoid complications when the top-down needle passage is utilized.

Although there are other types of RP slings available, TVT and SPARC continue to be the most widely used and have the preponderance of clinical data available in the literature.

Retropubic slings in the literature

The TVT procedure has been evaluated in a variety of randomized and nonrandomized studies during the past 10 years. In early articles and abstracts on TVT, Ulmsten *et al.* report on the outcomes of TVT in a variety of patients with SUI. In 2001, Ulmsten reported on 85 subjects who received TVT using local anesthesia with a mean follow-up time period of 56 months. He reported a cure rate of 85%, and 56% (14/25) were relieved of urge symptoms. Complications included *de novo* urge (6%), voiding dysfunction (4%), hematoma (3%), intraoperative bleeding (3%) and bladder perforations (1%) [21]. In 2004,

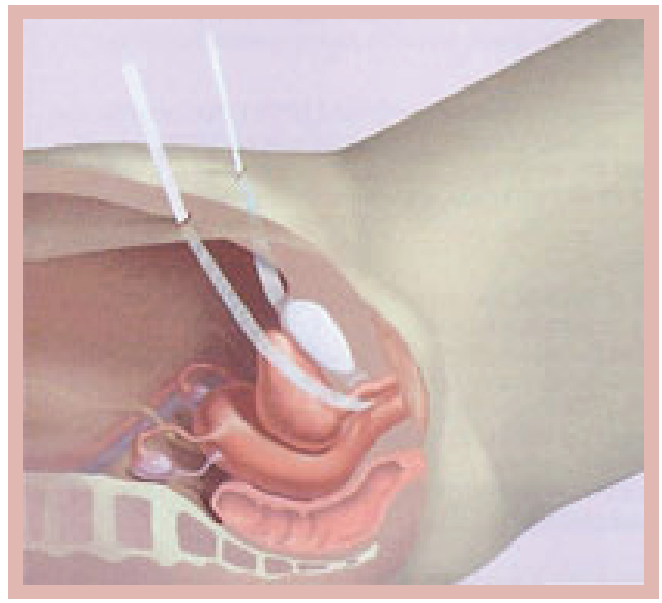

Figure 2. Tension-free vaginal tape by Gynecare (Johnson & Johnson).
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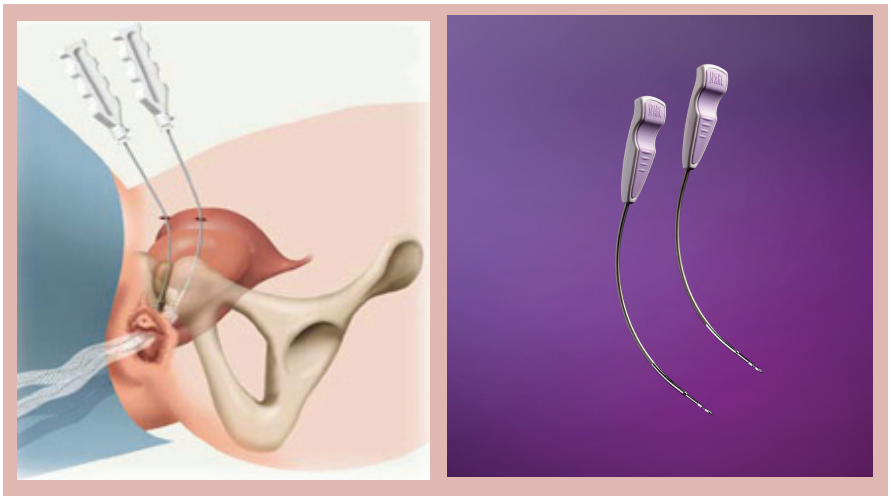

Figure 3. American Medical Systems SPARC™ sling system.

Nilsson *et al.* reported on successful long term cure rates of the TVT sling with a study of 90 patients with 7 year follow-up. They showed objective and subjective cure rates to be 81% using strict criteria for cure and concluded that the TVT sling continued to maintain its effectiveness to treat SUI over the long term [22].

In 2001, Ulmsten also reported on 80 subjects with mixed incontinence in a prospective study where subjects were followed for a mean of 4 years. In this series, he reported a cure rate of 85%, with 4% improved; 11% of the subjects were reported as failed. His conclusion was that the TVT sling could be used in patients with mixed SUI symptoms [23]. This confirmed earlier reports that the original intravaginal slingplasty procedure, from which the TVT sling was developed, was also effective in treating mixed incontinence [6,24]. Duckett, more recently, confirmed that even in patients with urodynamically proven detrusor overactivity (DO), the tension-free vaginal tape sling is an effective method to treat mixed incontinence [25].

Ulmsten also studied the outcomes of TVT patients with prior histories of intrinsic sphincter deficiency (ISD) and, in 2001, reported on 49 subjects enrolled in a prospective study with a mean follow-up of 4 years. In this study, ISD was defined as a mean urethral closure pressure (MUCP) of less than 20 cm H_2O. In this group of ISD patients, 74% (36/49) were reported as cured and 12% (6/49) were reported as improved. A total of 14% (7/49) were failures [26].

In 2001, Ulmsten evaluated patients with recurrent SUI. In a prospective study in 34 women (none with ISD), 11 of the patients had more than two previous procedures for SUI and three patients had more than five procedures. In a mean follow-up of 4 years, 82% (28/34) of subjects were cured and 9% (3/34) were improved. However, in this study, there was no discussion of urge symptoms [27].

In a 2002 study, Rardin *et al.* compared primary with recurrent SUI in 245 subjects; 157 patients with primary SUI and 88 with recurrent SUI. In this evaluation ISD was diagnosed in 47% of those with primary SUI and occurred in 70% of the recurrent SUI patients. There was no statistical difference in cure rates between the two groups: 85 versus 87% and, likewise, there was no statistical difference in their complications [28].

In a large, multicenter study of 1175 subjects, Rardin *et al.* evaluated patients who underwent the TVT procedure within a 2-year time period. Results demonstrated that 23 subjects (1.9%) had postoperative persistent voiding dysfunction consisting of either urinary retention, incomplete bladder emptying or severe urgency or urge incontinence that was refractory to conservative management. These subjects underwent a simple vaginal TVT release procedure that was performed on an outpatient basis. All patients were discharged on the same day as their release procedure, and there were no intraoperative complications associated. All cases of impaired bladder emptying were completely resolved and all patients with irritative symptoms were either resolved (30%) or improved (70%) by 6 weeks. In total, 14 patients (61%) remained continent 6 weeks after the release was performed, six (26%) were improved over baseline and three patients (13%) had recurrence of their SUI. The authors concluded that refractory voiding dysfunction post-TVT is relatively uncommon, but if it does occur, can be successfully managed by a simple vaginal midline release procedure [29].

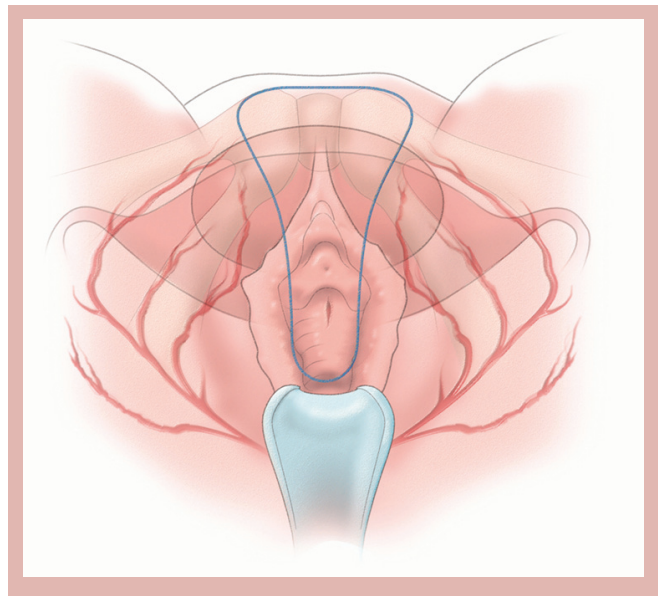

Figure 4. The 'safety zone' in the retropubic space, which avoids the major vessels is outlined in blue.
Adapted from Walters *et al.* [20].

In yet another study, Moore and Miklos looked at the outcomes of concomitant repairs of prolapse procedures and TVT in an elderly population. A total of 30 consecutive women had colpocleisis and TVT sling procedures without general anesthesia. Of these, 94% of the subjects were cured of their stress incontinence, and three women required reoperation for minor prolapse repairs. Their preliminary data suggested that TVT and colpocliesis could be performed concomitantly in an elderly population rapidly and safely with local anesthesia and mild sedation [30].

In the area of comparative studies, one of the more important studies has been the randomized, controlled trial (RCT) conducted by Ward and Hilton who compared TVT with the Burch urethropexy. Ward and Hilton, representing the UK and Ireland TVT Trial Group, reported on 344 women who were randomized to TVT or Burch colposuspension and followed out to 2 years [31]. This randomized study combined objective and subjective measurements; a 1-h pad weight test showed significant postoperative changes in both groups with the TVT group recording a negative pad weight test in 81% of the patients and 80% in the Burch group. Subjectively, using the Bristol Female Lower Urinary Tract Symptoms (BFLUTS) questionnaire [32], 20% in the Burch group reported no urine leakage under any circumstance while 25% of the participants reported this in the TVT group. The authors concluded that the TVT procedure is as effective as the Burch colposuspension in urodynamically proven patients with SUI at a 2-year follow-up. Ward and Hilton have recently published their 5-year outcomes in this study [33], where they reported a negative 1-h pad weight test in 58 out of 72 (81%) in the TVT group and 44 out of 49 (90%) in the colposuspension group. They stated in this latest follow-up article that the effect of both procedures on cure and improvement in quality of life has been maintained in the long term. Other subsequent randomized and nonrandomized comparative studies of TVT and published case series appear to be consistent with this large study by Ward and Hilton in that success rates vary between 74 and 97% [8].

In a more recent article, Novara *et al.* attempted to evaluate tension-free, midurethral slings by meta-analysis and systematic review of randomized clinical trials [34]. In their review of 37 RCTs, TVT subjects had better postoperative continence rates than those having the Burch colposuspension.

Studies evaluating mid-urethral tension free tapes that utilize an abdomen-to-vaginal approach, SPARC, have also been performed. Hodroff *et al.* reported on early outcomes of the SPARC procedure in 445 patients via a retrospective chart review [35]. A total of 83% of the patients on follow-up reported that they had complete resolution of all stress incontinence, similar to TVT results. More than 90% of the patients responded that they would undergo the procedure again. Complications included vaginal extrusions of the sling in 1.8% and bladder perforations in 6.7% of patients. Sling release procedures were performed in 19 patients (4.3%) due to large residual volumes or obstructive voiding symptoms. The most serious complication was a single bowel perforation in a patient who underwent cystocoele repair followed by the SPARC procedure. The authors concluded that, complications were relatively minor and infrequent and the procedure could be safely and routinely performed as an outpatient procedure [35].

In another study, 69 TVT patients and 37 SPARC patients were compared in a case-controlled series aimed at assessing sling placement, voiding function, bladder symptoms and patient satisfaction [36]. The authors found no significant differences for subjective cure/improvement (92% SPARC versus 85% after TVT). The authors noted that the SPARC sling was tensioned more loosely and this may promote less postoperative voiding impairment, fewer symptoms of voiding dysfunction and a higher likelihood of a positive clinical stress test. Finally, they observed that the SPARC product, which carries a central absorbable suture to allow for later adjustments, may prevent a tensioning phenomenon that has been noted during removal of the plastic TVT sheaths.

In a French multicenter trial for SUI using SPARC, Deval *et al.* evaluated the safety and efficacy of the procedure in 104 consecutive subjects who were implanted at three centers from June 2001 to June 2002. All women had urethral hypermobility (UH) preoperatively, and detrusor instability was ruled out urodynamically. There was a perioperative complication rate of 10.5%, including 11 bladder injuries. The authors noted that there was a difference in bladder injury rate between those patients who had had prior abdominal procedures versus those who had not. Voiding disorders were reported postoperatively in 11 patients. All cases were resolved in less than 15 days with intermittent self-catheterization. *De novo* urge symptoms were reported in 12 women. Objective cure rate was 90.4% and a subjective cure rate was noted to be at 72%. Deval *et al.* concluded that SPARC was safe and effective for women with SUI despite an observed high incidence of *de novo* urge symptoms [37].

In summary, the RP tension-free vaginal tape procedure (i.e., TVT or SPARC) has been the most studied procedure to date in the field of SUI, and this procedure has become the benchmark to be used to compare future treatments. It has been proven to be effective in both retrospective and prospective trials in primary SUI due to hypermobility and/or ISD, recurrent incontinence, mixed incontinence, ISD with fixed urethra and with concurrent prolapse repairs. There are proponents for each RP approach – TVT (bottom-up) versus SPARC (top-down). Many urologists find the top-down approach comfortable due to their prior experience with similar (e.g., Stamey or Raz) procedures. Gynecologists and urogynecologists may feel more ergonomic comfort with the bottom-up approach offered by TVT. Based on somewhat fewer data than TVT, SPARC appears to have similar efficacy to TVT. SPARC's complication rates are similar to other blind, needle-passing, RP procedures and may avoid major vascular injuries by hugging the pubic bone and staying within Walters' 'zone of safety' avoiding lateral needle excursions that may occur from a bottom-up approach (Figures 4 & 5).

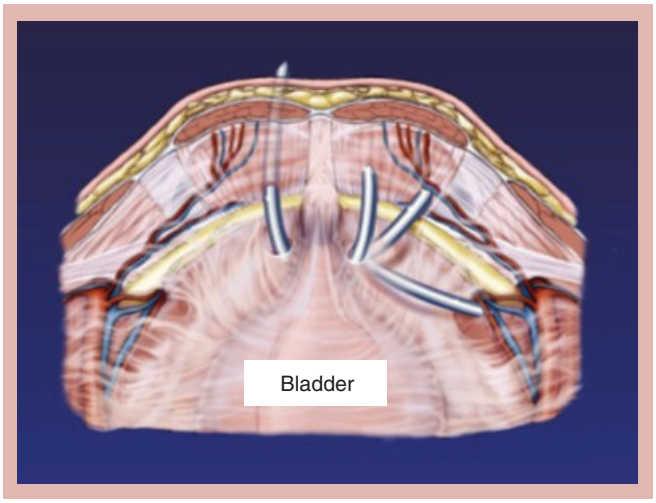

Figure 5. Retropubic needle passage for tension-free vaginal tape sling. Needle on the left shows a safe retropubic passage. Needles on the right show potential damage to abdominal/ pelvic vessels and nerves.
Reproduced from Walters *et al.* [20].

Transobturator slings

Although cure rates were excellent with the RP approach, such as the TVT and SPARC, there were also complications associated with the blind needle passage through the RP space including bladder perforation and nerve injury, as well as major vascular and bowel injuries. A less invasive approach was developed by Delorme and others in Europe to try to minimize these complications [38]. This approach maintained the mid-urethral support placement, but used needles inserted through the groin via the obturator foramen rather than through an abdominal route.

This anatomic TO approach to the midurethral location promised to further minimize complications observed with earlier RP procedures for SUI.

Since its introduction, the TO approach has increased in popularity, with the ease of the approach and its inherent safety features. The TO sling has been shown to be an effective minimally invasive procedure for SUI with studies showing cure rates between 85 and 95%, with seemingly fewer complications compared with the RP approach [39–41]. These TO approaches eliminate the need to blindly pass a needle through the RP space and, therefore, minimize the risk of major vascular, bladder or bowel injury. Additionally, the TO sling lies in a position that mimics the pubourethral ligament and is thought to cause less voiding dysfunction or obstruction than the RP slings (Figure 6).

The two most widely implanted TO slings are the Monarc Subfascial Hammock (AMS) and TVT-O (Johnson & Johnson). Other TO slings are available in the increasingly competitive medical device industry, but Monarc and TVT-O have the majority of articles in the literature.

The Monarc Transobturator Sling utilizes patented helical needles passed from the outside of the groin into the vagina with direct finger guidance and a 4–0 polypropylene monofilament mesh tape (Figure 7). This helical-shaped needle is designed to follow the line of the pubic bone and thus allows the surgeon to protect the bladder and urethra during rotation of the needle into the vagina with the outside-in approach. The sling material is the same material used in the SPARC and TVT procedures, which has been shown to be very well tolerated in an estimated 1 million cases worldwide. Gyenecare's product, TVT-O, utilizes needle passage from the inside of the vagina out into the groin (Figure 8). This passage route requires the needle to exit laterally in the thigh in the region of the obturator neurovascular bundle. Zahn *et al.* conclude in their March 2007 article that the outside-in approach results in the sling mesh being placed farther from the obturator canal (i.e., closer to the ischiopubic ramus) which, in theory, should minimize the risk of neurovascular injuries [42].

Monarc in the literature

The longest prospective study data available on the TO procedure is reported by DeRidder *et al.* who have collected 24-month data on 147 patients enrolled in a multicenter prospective, nonrandomized study at 15 sites in Europe, Canada and Australia [43]. Objective efficacy was evaluated by cough stress test, pads per day and the 1-h pad weight test. Subjectively, efficacy was evaluated by the Urogenital Distress Inventory Short Form (UDI-6) and the Incontinence Impact Questionnaire Short Form (IIQ-7). A total of 87.6% of the patients at 24 months had a negative cough stress test and there were no incidents of vascular, bowel or bladder perforations or hematomas reported. In total, 99.3% of patients went home without a catheter. There were three (2.0%) reported incidents of mesh extrusion in the study.

In addition to DeRidder's international clinical data on 147 Monarc patients, there are US clinical data obtained on 117 Monarc patients. A subsequent combined international/US

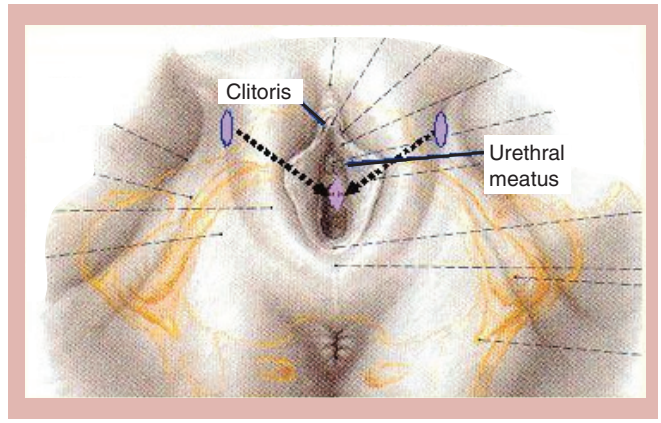

Figure 6. Transobturator sling 'hammock' position. Dotted arrows show the final position of the transobturator sling placement. The blue circles in the groin are where the small stab incisions are made to place the polypropylene mesh tape sling.
Adapted from [101].

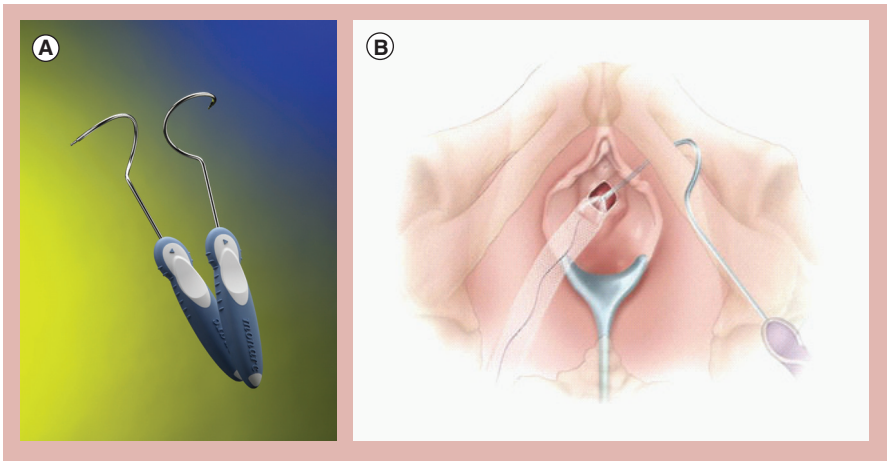

Figure 7. (A) Monarc™ Transobturator Needles and (B) The Monarc Sling.
Courtesy of American Medical Systems, Inc. [102].

data summary was the first worldwide multicenter prospective study to report on the results of the Monarc TO sling procedure. In this combined US and International prospective study on the Monarc Sling, Moore *et al.* reported on 264 subjects with the mean age of 56.6 years who underwent this TO surgical procedure [44]. The procedure time to implant the mesh only was 13 min (range: 1–107 min), and the average estimated blood loss (EBL) was 35 ml (range: 2–250 ml) for the Monarc portion of the surgery only. EBL was assessed only in the US group of 117 patients. Time to void without catheter was an average of 13 h (range: 0–144 h), and 234 subjects (89%) were discharged without a catheter. Of the 264 patients, only four (1.5%) reported complications of short-term pain and/or numbness in the groin, leg or thigh area, which resolved spontaneously in all four patients. A total of eight (3.0%) had *de novo* urge symptoms or incontinence, 12 (4.5%) had urinary tract infections (UTI) and ten (3.8%) had increased residuals or urinary retention. There were four (1.5%) mesh extrusions requiring surgical intervention or revision with two (0.8%) subjects having extrusions that required no surgical intervention or only minimally invasive therapy.

Although there have been other retrospective and prospective studies reporting on results of the TO sling procedure, this has been the first worldwide, multicenter, prospective study to report on the Monarc TO sling procedure. The study is unique as it involves many sites from throughout the world giving the study the strength of multiple surgeons from different sites, with all sites showing very similar results of safety and efficacy with the procedure. There were 22 sites reporting on data worldwide with 26 surgeons involved, which gives the study not only strength of numbers but also reports on how the procedure consistently performs in many various countries and institutions. The results help to demonstrate that the procedure can be performed in many different conditions and countries by surgeons with different backgrounds, training and the results are still very consistent with what we have seen in the literature to date.

Intraoperative safety and complications are a major concern of any surgical procedure. In contrast to the reports of major vascular, bowel and bladder injuries resulting from the blind passage of needles through the RP space with traditional tension-free procedures, TO needles remain below the endopelvic fascia and do not enter the RP space or abdominal cavity. The TO approach appears to be a safer needle passage for a mid-urethral sling. In this prospective study, there were no bladder or bowel perforations or major vascular injuries resulting in excessive bleeding or bleeding requiring transfusion.

Previous studies have demonstrated a risk of bladder perforation with RP tension-free procedures, ranging from 2.7 to 15% [19,45]. The anatomic position of the TO sling is believed to significantly mitigate this risk, and this belief was further supported by the results of this study. Although there have been case reports of bladder injuries with larger 'hook' type or Emmett needles [46] used with some TO systems, the overall risk of bladder injury with the TO approach is thought to be considerably less than with traditional RP type procedures.

Likewise, a retrospective, multicenter US study involving 200 Monarc patients at three sites (Davila *et al.*) reported no urethral, bladder, bowel or vascular trauma, which occurred during the study with Monarc [41]. A total of 95.3% of Monarc

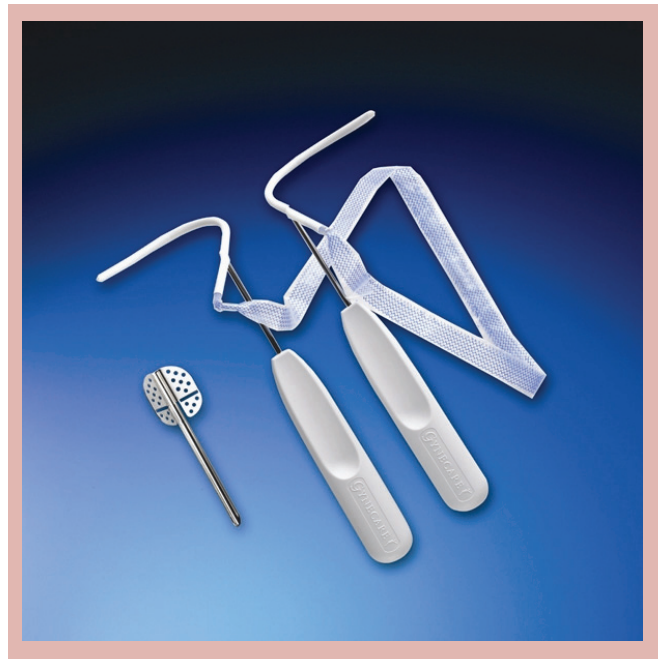

Figure 8. Tension-free vaginal tape-obturator from Gynecare.
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patients with 26 weeks of follow up were reported as cured. In addition, 20.5% reported urge symptoms after the procedure compared with 62.7% at baseline. No Monarc patients reported worsening urgency postoperatively. There were no patients who reported groin pain, new onset of sexual dysfunction or tape infections or erosions in this retrospective study.

There are several comparative studies that discuss Monarc and TVT tension-free vaginal tape and have shown equivalent cure rates between the procedures. Mellier first reported on a retrospective cohort of patients that underwent the Monarc procedure (n = 94) and compared the results with a prior group of patients undergoing the TVT procedure (n = 99). Mean follow-up was 29.5 months in the TVT group and 12.8 months in the TO group. He found more bladder perforations and hemorrhagic complications in the TVT group when compared with the TO group but found equivalent cure rates of 90 and 95%, respectively, at 1 year [39].

Barber *et al.* evaluated intraoperative and postoperative complications in 418 subjects implanted with either the Monarc TO sling or TVT between January 2003 and August 2005. A total of 205 women underwent the Monarc procedure while 213 were implanted with TVT. There were more bladder perforations (5%) in the TVT group compared with none in the Monarc group. Additionally, the TVT group were more likely to require urethrolysis for voiding dysfunction postoperatively and were more likely to use anticholinergics than the TO sling patients. Owing to the retrospective nature of the study and its short term follow-up, the authors did not compare rates of efficacy between the two groups [47].

In a multicenter, randomized trial comparing TVT with the Monarc TO sling, Barber *et al.*, in this case, randomized 180 subjects to either procedure at three academic medical centers. Patients with detrusor instability or prior sling procedures for SUI were excluded from the study. Of these, 170 underwent the procedures and 166 returned for follow-up. Furthermore, bladder perforations occurred more frequently in the TVT group (7 vs 0%), and the TVT group had a higher incidence of abnormal postoperative bladder function (46 vs 42%). Both groups had similar negative cough stress test results 1-year postoperatively (90% TVT and 91% Monarc). SUI symptoms were also reported similarly postoperatively in both groups at 15%. The authors concluded that the Monarc TO sling was not inferior to TVT and results in fewer complications of bladder perforations [48].

Botros *et al.* reported on the rates of resolution of DO and subjective urge urinary incontinence (UUI) as well as *de novo* DO and UUI in patients implanted with Monarc and the RP slings of SPARC and TVT [49]. The study was the first of its kind to study the ongoing and/or *de novo* neurological changes to bladder function after insertion of either the TO Monarc sling or the RP slings of TVT and SPARC. The authors found that *de novo* subjective UUI differed significantly between the TO Monarc sling patients versus the two other retropubically placed slings with less *de novo* UUI occurring in the Monarc patient group. A total of 14–16% of retropubically placed slings (SPARC/ TVT) with preoperative UUI had worsening of their UUI symptoms while only 6% of the Monarc patients did. The Monarc procedure significantly increased the chance of resolution of UUI over the TVT or SPARC procedures postoperatively.

The authors of this study admit that they are not certain why the TO sling approach resulted in improved rates of *de novo* UUI. They hypothesize that the cause could potentially be from the location of the suburethral sling, as discussed in an earlier article by Deitz *et al.* (2004) who described observing an increase in urgency and DO in patients who had a more cranial (towards the urethral meatus) location of their RP midurethral slings, as observed on pelvic ultrasound [50]

Alternatively, it is possible that the TO approach for sling placement produces more of a hammock-type of sling location due to the lateral arms of the TO slings that go more laterally to the genitofemoral crease when compared with the more U-shaped configuration of the RP slings, as discussed by Whiteside and Walters in 2004 [51].

In theory, the increased surface area of the slings contacting the urethra with the RP approach or the position of the sling having a more acute angle with the RP approach versus the TO hammock, may create more circumferential compression and lead to a higher risk of obstructive type symptoms.

TVT-O in the literature

Lim *et al.* assessed the success rate of TVT-O in a prospective observational study of 100 patients who underwent the procedure in a 6-month period from March to October 2004 [52]. Objective success rates were 95% at 6 months and subjective success rates were reported at 92 and 84%, respectively, which were comparable to RP TVT and Burch colposuspension procedures. There were no reports of bladder, vascular or visceral injuries reported in this study, which appeared consistent with other TO sling procedures. There was a 1.1% rate of paraurethral vaginal mesh extrusion that is comparable to other RP sling series reports of 0.4–4.1%. The authors conclude that TVT-O is a safe and effective treatment for female SUI. In one of the longest follow-up studies to date, Waltregny *et al.* recently reported successful data on TVT-O at 3-year follow-up confirming reports of earlier reports with shorter follow-up [53].

One of the more interesting discoveries in the Lim paper is related to postoperative groin pain. The authors state that the most prevalent complication or complaint within the first 6 months postoperatively was groin pain or discomfort which was found in 22 women or 24.4% of the patients. Although the figure was markedly reduced at the 12 month assessment, three women (3.7%) continued to have persistent groin pain.

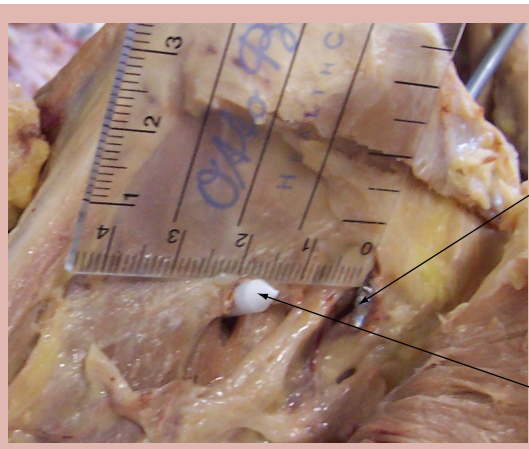
Groin pain & TO tape slings

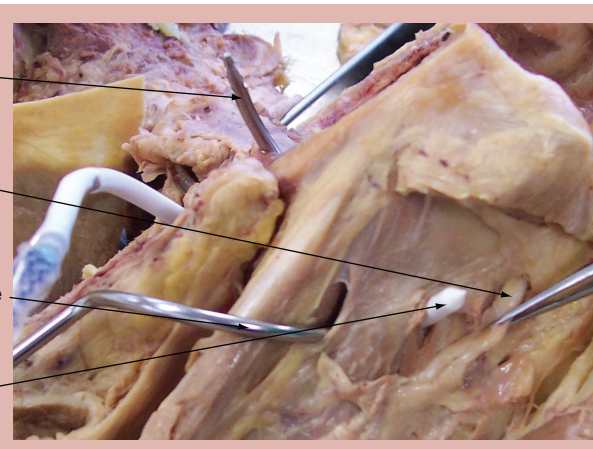
Despite the less invasive approach of the TO tape (TOT) sling and its encouraging clinical results, the procedure has not been proven to be risk free. One of the concerns of the procedure is

the development of clinically significant groin pain following the passage of needles and mesh through the TO space and the medial groin beneath the adductor longus tendon. This appears to be more of an issue with the 'inside-out' approach that the TVT-O utilizes. Studies have demonstrated risks of postoperative groin pain with the TVT-O procedure in the range of 15–24%, with as much as 4.7% of patients complaining of long-term pain [52,54]. The risk of groin pain has been shown to be much lower with the outside-in approach, including the Monarc procedure [41,43]. With this approach, the incision in the groin is made in the genitofemoral crease, approximately 3 cm away from the obturator canal, and the needle is then passed through this incision and directed away from the canal and the neurovascular bundle, following standard surgical safety principles. With a vaginal-to-groin approach, such as the TVT-O, the needle is directed from the vagina out towards the obturator canal and the neurovascular bundle without direct finger guidance. Given the angle of the pubic bone, with this type of approach the exit point of the needle in the groin is much more lateral to the genitofemoral crease and closer to the obturator canal when compared with the Monarc needle entry point, which may increase the risk of injury to nerves or vessels that traverse the obturator canal. The trajectory of needles and their entrance and exit points and how this may affect safety have been further described in several studies (Figure 9) [19,51,55].

Leg or groin pain is mentioned in several other series in the literature. Laurikainen *et al.* discuss their findings in a randomized, multicenter comparative trial of intraoperative and immediate postoperative performances of TVT and TVT-O [54]. Their trial was designed to uncover any differences in success and complication rates when using identical suburethral tapes but using the different surgical approaches of RP versus TO. A total of 267 patients underwent the procedures with 136 subjects randomized in the TVT group and 131 in the TVT-O group. Contrary to what the authors expected, they did not find a lower rate of complications with the newer TVT-O procedure. Patients in the TVT-O group had a significantly longer hospital stay (17 vs 14 h [p = 0.027]), needed significantly more postoperative opiate analgesia due to pain (28 patients compared with 16 [p = 0.034]) and had more complications than the patients in the TVT group. Specifically, the number of patients complaining of postoperative groin pain was greater in the TVT-O group when compared with the TVT group (16% for TVT-O vs 1.5% with TVT). They also found that the return to normal voiding was significantly more rapid in the TVT group than the TVT-O group. These findings seem to contradict the findings of (or these findings do not seem to be consistent with) most of the TOT approaches that utilize an outside-in approach and, therefore, it may be secondary to the needles being passed from the vagina out into the groin that brings the needle much closer to the obturator neurovascular bundle.

Additionally, several papers/posters presented at the International Urogynecological Association (IUGA) 31st Annual Meeting, September, 2006, in Athens, discussed the complication of leg pain in patients undergoing the TVT-O procedure [56–59].





Device	Median [range] (mm)	Mean ± standard deviation (mm)
TVT	40 [33–45]	40.1 ± 3.7
TVT-O	18 [17–26]	19.3 ± 3.06
Monarc™	25 [22–35]	26.9 ± 4.07

Comparison	Difference (mm)	95% confidence interval (mm)	p value
TVT–TVTO	20.8	17.6–24.0	<0.0001
TVT–Monarc™	13.2	9.5–16.8	<0.0001
Monarc™–TVTO	7.6	4.3–11.0	<0.0002

Figure 9. Distances between TVT/TVT-O/Monarc™ and Obturator Canal differ significantly. TVT-O is closest to vital vessels, on average 7.6 mm closer to obturator vessels than Monarc. While Monarc's approach veers its needles away from Obturator Canal, TVT-O's needle path goes towards obturator vessels.
TVT: Tension-free vaginal tape.
Data from [55].

Collinet *et al.* report on 994 female subjects in a prospective, multicenter study of the French TVT-O Registry [56]. In this analysis, 14.8% of the patients reported moderate pain postoperatively who received the TVT-O procedure. In most cases (62.8%), pain was located bilaterally and in the upper thigh in 70.9% of those reporting pain. Lin *et al* [57]. reported on 32 consecutive patients undergoing the TVT-O procedure with 11 (34.4%) of the patients reporting thigh pain postoperatively. In yet another study, Han *et al* [58]. report on a group of 61 patients who were randomized to the TVT-O procedure and 61 patients who were assigned to the TVT procedure. In this study, a significant number of subjects post-TVT-O compared with the TVT group (55 vs 10 patients) complained of wound aching and pain.

Finally, Groutz *et al.* report on 55 consecutive patients undergoing the TVT-O procedure with five patients (9%) who had protracted thigh pain postoperatively [59]. Of these patients, four out of five had spontaneous improvement of thigh pain symptoms within 3 months after the procedure.

In addition to groin or thigh pain that may occur postoperatively, surgeons should be aware of the rare possibility of groin abscesses secondary to TO sling infections. Marsh and Rogerson [60] discuss a case report of a 46-year-old patient who developed a left lateral vaginal wall tape erosion, which later developed into a groin abscess after sling excision and removal. These cases do appear uncommonly but may create added interest in the new mini-sling approaches that avoid groin and leg tape passages.

The one area that the RP approach has been demonstrated to remain superior to TOT is in patients that have a fixed urethra and ISD. This is thought to possibly be secondary to the more obstructive nature of the angle of the RP approach and, therefore, many surgeons are still utilizing the RP tension-free slings in these types of patients. Guerette *et al.* discuss their findings recently in a study designed to evaluate preoperative urodynamic urethral function measurements used to predict success rates of TO slings [61]. In this study, 70 patients with urodynamically diagnosed SUI secondary to UH undergo the Monarc TO procedure. Average follow-up was 8.1 months, and 56 (80%) of the patients were continent as measured by cough test and subjective assessments. Those patients who failed had median valsalva leak point pressures (VLPP) of 32 cm H_2O compared with 71 cm H_2O in the patients with success. Similar rates were observed in the maximum urethral closure pressure (MUCP) between failed and successful outcomes. This indicates that the one area that the TOT sling may not be as effective as the RP approach is in patients with low urethral closure pressure or ISD.

Cystoscopy should be completed in all patients undergoing RP slings for obvious reasons (i.e., the risk of bladder perforation during needle passage). If recognized immediately, there are typically no sequelae, and the sling can still be placed without difficulty with no long-term consequences. However, if the bladder is not totally distended and the perforation missed, the results can be severe as the mesh acts as a foreign body in the bladder causing recurrent infections, pain, urgency, frequency and, ultimately, will need to be removed, which can be a major surgical intervention. Initially, the TO approach was developed to help minimize the risk of bladder injury, and it was felt that cystoscopy may not be necessary with this approach. However, even though the risk of bladder injury is much less with the TO approach, bladder injuries have been reported. Therefore, surgeons should consider cystoscopy to rule out bladder injury especially when first learning the technique and during any case where the needle passage and/or dissection is not clean and straightforward. Ultimately, risk of complications and also success depends upon the experience of the surgeon completing the technique of any sling. There will always be a learning curve with any surgical technique, and although this learning curve has been getting shorter with the advent of new technology in sling procedures, it is still present. Overall success rates will still be linked to surgical experience no matter how great the technology.

In an effort to make sense and give perspective to the plethora of articles and information on the variety of slings available, three meta-analyses were published during 2007 discussing RP and TO slings. The first of these articles by Latthe, Foon and Toozs-Hobson was published in March 2007 [62], and compared TO and RP sling procedures discussing their individual complication rates as well as rates of effectiveness. A total of 11 RCTs with 1261 female subjects were included in the review. Five of the trials compared TVT-O (inside-out approach) with TVT, and six trials compared TOT (outside-in approach) with TVT.

Results of subjective cure rates when compared with TVT were equivalent in the TOT group and slightly worse in the TVT-O group of patients. Bladder injuries and postoperative voiding difficulties occurred less in the combined TVT-O/ TOT groups when compared with TVT patients. However, vaginal injuries/erosions were reported twice as often in the TO group. Also, reports of groin/thigh pain were greater in the TO groups than the TVT patients.

The second meta-analysis paper on tension-free, mid-urethral slings published in June, 2007, was by Novara *et al* [34]. Their search identified 37 RCTs, and the article looked at mid-urethral slings in comparison with other surgical techniques for SUI including the Burch colposuspension, pubovaginal slings, RP slings and TO slings. As discussed previously, they concluded that TVT outperformed Burch colposuspension in postoperative continence rates, and efficacies were similar for TVT and pubovaginal slings. The review showed overlapping cure rates for RP and TO slings.

Finally, the third meta-analysis article, again by Novara *et al.*, was published in November, 2007 [63], with the objective to evaluate the complication rates of tension-free, mid-urethral slings when compared with other surgical procedures. In their review of 33 RCTs, they concluded that complication rates between TVT and Burch colposuspension were similar (excluding bladder perforations and reoperative procedures). TVT and pubovaginal slings had similar complication rates. They observed more voiding

lower urinary tract symptoms (LUTS) and reoperations after SPARC procedures when compared with other RP tension-free slings. They also concluded that the incidence of pelvic hemotomas, bladder perforations and storage LUTS was significantly lower in patients with TO slings.

All three articles voiced a common plea for higher-quality studies with standardized criteria and longer term follow-up periods.

Due to the benefits of the TOT approach, it has become the primary mode of treatment for female SUI in many centers. However, despite a less invasive approach, better safety profile compared with blind RP needle passage and seemingly comparable cure rates in all situations except possibly patients with ISD, risks such as groin pain still do exist with the TO procedures. Therefore, the search for even less invasive treatment options continues to be ongoing.

Mini-slings

The latest in the logical progression of synthetic slings used in the minimally invasive treatment of SUI is the mini-sling. Barring the complication of groin pain, the risk of TO sling complications appeared to be very low. However, the next step towards a less invasive, mid-urethral tension-free sling was to develop a system that could be placed through one small vaginal incision without having to pass needles through the abdomen or groin.

There are two 'next-generation' single-incision mini-slings that currently have the most visibility in the marketplace, the TVT-Secur System (Johnson & Johnson) and the MiniArc™ Single Incision Sling (AMS). Johnson and Johnson, Gynecare, developed the first mini-sling that was released in the USA in autumn 2006 and is called the TVT-Secur. With the TVT-O causing seemingly high rates of groin pain, investigators were searching for an alternative that could reproduce the benefits of the TO sling, but reduce the risk of groin pain observed with TVT-O. The TVT-Secur device utilizes a single vaginal incision to place a sub-urethral macroporous polypropylene mesh tape (the same mesh as used with TVT, TVT-O, Monarc and SPARC) without exit wounds. The product can be placed either in a U-shape, similar to the TO tape position, or a V-shape, similar to the RP tape position. No needles are required to pass through the abdomen or groin. However, there is a metal blade/trocar attached to the ends of the mesh to pass it into either the obturator fascia and muscle or the RP space. Once the sling is in position, the metal blade/trocar needs to be released and separated from the mesh, while attempting to keep the mesh in position. The ends of the mesh are laminated with Vicryl™ and polydioxanone (PDS) fleece jackets, designed to keep the sling in place after healing (Figure 10).

The latest mini-sling is the MiniArc™ Single-Incision Sling from AMS. The product obtained US FDA approval for market distribution in March, 2007, and the MiniArc Sling involves a minimally invasive procedure similar to the Secur product. The MiniArc Single-Incision Sling has several modifications over the currently available mini-slings on the market intended to make it easier to place and achieve immediate fixation for mid-urethral

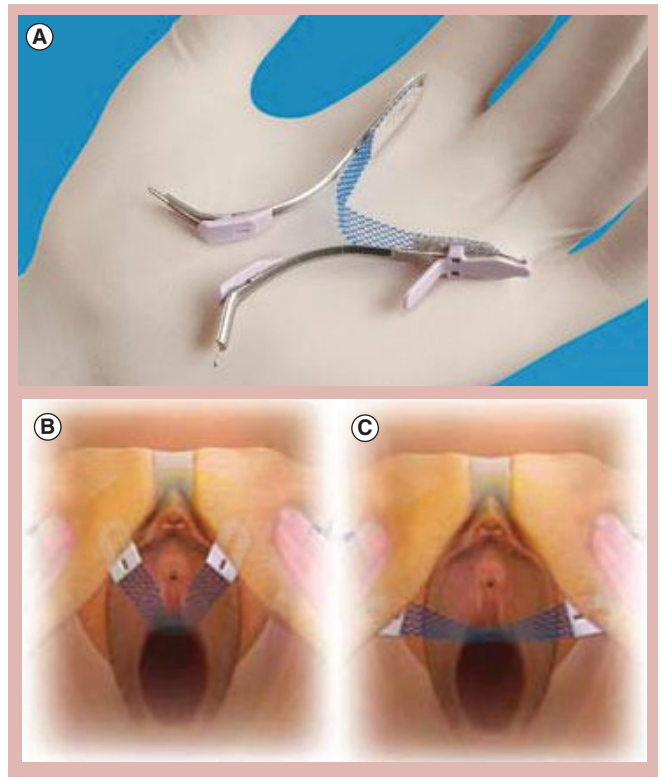


Figure 10. TVT-Secur Sling (A) in both the V- (B) and U-shaped (C) configurations.

placement of the mesh tape sling. The MiniArc sling kit is comprised of an 8.5 cm monofilament macroporous polypropylene mesh (the same mesh as in Monarc and SPARC) with small, integrated self-fixating tips that are made of polypropylene, and a curved needle that fits into the self-fixating tip for advancement and placement of the sling that removes from the self-fixating tip once final positioning of the tape is achieved. Bench testing indicates that the average pull-out strength to remove the sling from the obturator muscle is 5.5 lbs of force which is four-times the normal pelvic floor pressures, which equates to approximately 1.3 lbs of force (Figures 11 & 12) [64,65].

Limited clinical data

Owing to the relatively new market introduction of the mini-slings (TVT-Secur in 2006 and AMS MiniArc, 2007), there are limited published data available for either of these new product entries.

Overall, short-term results with the TVT-Secur, have not been very encouraging and have not been shown to be as effective as either the RP or TO sling approach. Cure rates have been reported in the range of 69–83% in short-term follow-up with a significant learning curve reported to be required for maximal results [66,67].

In a recent abstract, Saltz *et al.* report on 105 TVT-Secur patients evaluated in a retrospective chart review [66]. The purpose of the study was to describe short-term efficacy and perioperative outcomes related to insertion of the new TVT-Secur

Figure 11. MiniArc™ Sling by American Medical Systems. Note the self fixating tip at the end of the macroporous polypropylene tape. Studies on pullout strength have shown the fixation is equivalent to Monarc™ transobturator tape sling. Once the tip is fixated into the obturator muscle, the needle slides out easily.
Courtesy of American Medical Systems, Inc. [102].

sling for SUI. Procedures were performed under local/regional anesthesia with sedation at two separate institutions. A total of 55 patients received the 'U' type of placement while 50 patients were given the 'hammock' configuration. All patients reviewed had at least a 6-week follow up.

In total, 75 (71.4%) displayed no postoperative SUI, while 30 (28.6%) of the patients had persistent SUI, of which 20 were significantly improved when compared with their preoperative status and refused further treatment. There were ten (9.5%) true failures with ongoing SUI who required further treatment. Only one patient (0.95%) complained of pain at 6 weeks, which had resolved at the time of writing the abstract. The last 25 patients to receive the TVT-Secur demonstrated a higher cure rate of 80%, which may indicate that there is a learning curve in adopting this new procedure. There were no mesh exposures reported.

The authors concluded that the Secur product provides a significant decrease in postoperative pain when compared with traditional RP and inside-out (vaginal to groin) TO sling procedures. The product appears to be efficacious and has a learning curve involved with surgical placement. However, its cure rate is relatively low compared with the RP (i.e., TVT) approach or the TOT approach.

Other recent TVT-Secur studies that were presented at the 2007 International Urogynecological Association Meeting (IUGA) also exist (Table 2).

The cure rates from TVT-Secur are not as high as those observed with the TVT/SPARC approach or the TOT approach [67,68]. Additionally, others have reported difficulty in releasing the trocar/blade away from the mesh, once placed into position that may affect cure rates. The TVT-Secur mesh does not have self-fixating tips and therefore it may have the potential to move or loosen during the initial postoperative period prior to tissue ingrowth for fixation of the sling. Concerns have also been raised with the size and sharpness of the sharp-tipped trocar utilized to place the mesh with TVT-Secur and the risk of bleeding or bladder injury.

To date, there has been one study completed on the MiniArc sling with the lead author of this review being the principal investigator; a retrospective study in five US centers evaluating the first 60 patients implanted with the MiniArc sling. These results were presented in abstract form at the American Association of Gynecologic Laparoscopists annual scientific meeting in Washington, DC in November of 2007 [69]. Unpublished preliminary

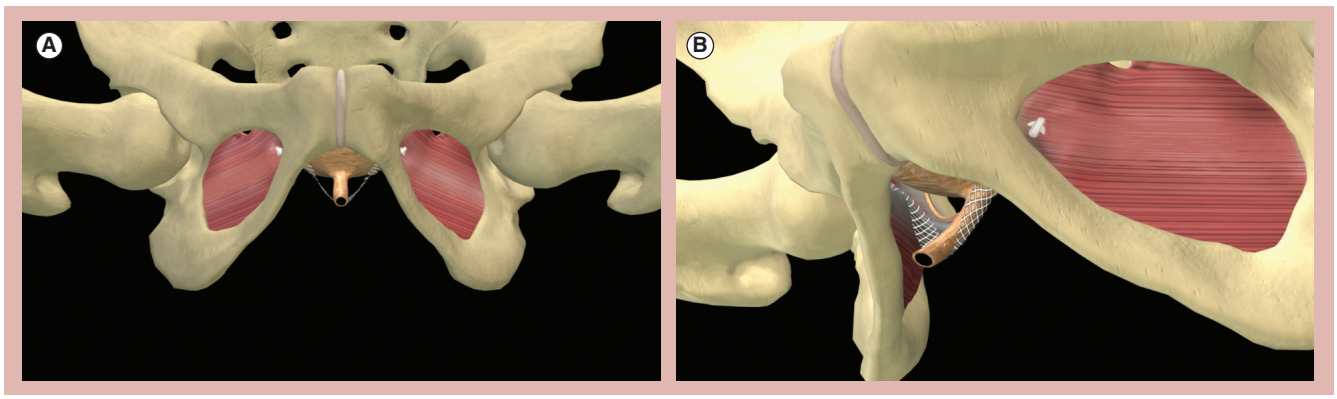


Figure 12. MiniArc sling position. (A) The MiniArc sling in a bony pelvis. The 'hammock position' mimics the transobturator sling. **(B)** Lateral view of MiniArc sling in place with self fixating tip in obturator internus muscle.
Courtesy of American Medical Systems, Inc. [102].

Table 2. TVT-Secur™ Abstracts from International Urogynecological Association 2007 Annual Meeting.

Study	n	Follow-up	Cure	Complications	Comments	Ref.
Karram *et al.*	72	5 weeks	75% (objective)	Device placement difficulties (three)	Caution with inserter removal	[67]
Albrich *et al.*	24	18 weeks	83.3% (objective) 44.4% (absolutely dry)	Additional surgery (three)	Six patients lost to follow-up	[68]
Assassa *et al.*	40	6 weeks	74%	Button-holing (two)	Mean overall response time: 17 min	[71]
Salz *et al.*	77	6 weeks	68.8%	–	Mean overall response time: 26.3 min; 'real learning curve'	[66]
Han *et al.*	30	1 month	67% (cure not defined)	Bladder perforations (one)		[58]

Abstracts presented at: *The 32nd Annual Meeting of the International Urogynecological Association (IUGA).* Cancun, Mexico, 12–16 June 2007.

results on 57 out of 60 (95%) of the patients who completed 12-week follow-up visits demonstrate an average procedure time of 7 min and minimal EBL at 27 ± 16 ml [Moore RD, Unpublished Data]. There were no intraoperative complications reported. Postoperatively there were no reports of groin pain, no mesh extrusions or urinary obstructions requiring dilation, no loosening or release of the sling. None of the self-fixating tips could be palpated on vaginal exam. Only two of the 60 patients required catheter for more than 3 days and both were voiding normally by day 7.

Preliminary SUI cure at 12 weeks, was observed in 55 out of 59 (93.2%) of the subjects who were confirmed dry by either cough stress test or by physician assessment. Subjective cure rate for SUI was 93.3% (UDI-6 score of 0 or 1). Urinary urgency and frequency symptoms were significantly present in 77.5% of patients pre-operatively and in only 8.8% of patients post-operatively. Patient quality of life was also significantly improved after Mini-arc sling placement with QOL scores (IIQ-7 and UDI-6) showing statistically significant improvement on both assessment questionnaires. The short-term cure rate of the MiniArc appears to be comparable to the TVT/TO approach without the risk of needle passage through the groin or abdomen. The authors felt that the seemingly higher cure rate of this mini-sling, when compared with the results being seen in the TVT-Secur trials, may be secondary to the immediate fixation of the tape with the self-fixating tips into the obturator fascia and muscle and the easy release of the needle away from the tip.

Expert commentary

Understanding the past not only helps in appreciating how far we have come but may also indicate that change comes with a price: metaphorically and realistically. Advances in surgical treatment for SUI via pubovaginal slings have provided physicians and patients with many opportunities and advantages:

- Decreased surgical time
- Decreased patient morbidity and shortened recovery time
- Improved outcomes including quality of life
- Limited and/or acceptable complications

Treatment for female SUI has seen revolutionary changes in the last 10 years with new minimally invasive techniques that have been proven safe and effective. The TVT sling was developed first and then the TOT sling followed, which provided a safer means to place a tension-free mesh tape sling, with seemingly equivalent cure rates and lower rates of voiding dysfunction. Undoubtedly, even with the advent of single-incision mini-slings, the search for newer procedures and technologies will continue.

But as we have seen with the advancements that have evolved over the last decade, there can sometimes be confounding side effects and unforeseen consequences caused by the changes created by new and improved technologies. RP slings clearly offered distinct advantages over the earlier RP urethropexy-type procedures in minimizing the surgical incisions and decreasing postoperative morbidity, but sometimes produced complications by perforating unwanted tissues during the procedure. Likewise, the TOT sling has not been totally risk-free, as groin pain has been reported in some series, especially with the inside-out approach. It is too early to comment on the mini-slings as to any possible unforeseen complications that may occur when the product is implanted in a volume of patients and thus further study via RCTs are indicated.

There appears to be one remaining fact – that female SUI will be an ongoing pathology in need of improved treatment options and more efficacious outcomes with minimal patient morbidity.

Five-year view

Technologies for the treatment of female stress urinary incontinence will certainly not stop with the latest advent of commercial slings – the mini-slings. Anecdotal and early scientific reports of positive outcomes with short term follow up seem to reinforce the idea that the mini-sling concept may be the next generation of pubovaginal slings for female SUI. It may well be that this new technology is the next obvious step in the 'smaller-is-better' trend seen in some product developments.

The next step beyond the needle less, single small vaginal incision technique could be the total elimination of any skin incision. Although treatment of female SUI without surgical

intervention may be heresy to surgeons, patients would be eternally grateful to avoid the knife regardless of how small the incision has become.

Other methods for supporting the urethra for SUI may be forthcoming. Recent developments in radiofrequency technology have created opportunities in controlled scarring of paraurethral tissue in an effort to create support for the hypermobile urethra [70]. The Renessa™ (Novasys Medical, Inc., CA, USA) device utilizes radiofrequency to heat the inside of the urethra to treat mild SUI in the office setting. In at least one of the author's opinions, the procedure may provide 'gap' coverage for women who want to delay definitive treatment of SUI that requires surgical intervention or for women with just mild SUI, since the current results do not seem to support use in more severe SUI.

The future certainly may hold improvements in technology such as radiofrequency treatment that can be utilized in the office without incisions and/or technologies, such as stem cells, that may be able to be injected in or around the urethral support structures and provide regeneration of the lacking support structures. It is hard to imagine any further improvements in the mid-urethral sling procedures or surgeries for SUI; however, we were certain that 10 years ago, no-one could have imagined the progress and development that has been seen over these few short years in the treatment of SUI.

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Key issues

- Female stress urinary incontinence (SUI) is a major health concern affecting at least a quarter of women between the ages of 30 and 60 years.
- During the last decade, there has been a steady progression and evolution of synthetic slings used to treat SUI.
- The modern-day sling was based on the landmark hypothesis of the integral theory from Petros and Ulmsten.
- Three types of synthetic slings currently dominate the medical market for treating SUI: retropubic, transobturator and single-incision/mini-slings.
- Material used for most synthetic slings currently utilize the preferred monofilament-knitted polypropylene material (i.e., type I mesh).
- Retropubic tension-free vaginal tape procedures have the preponderance of clinical data representing a benchmark for subsequent sling approaches.
- Transobturator slings avoid the blind retropubic needle passage and provide a less invasive approach; however, risks of groin or thigh pain still exist.
- Single vaginal incision slings (i.e., mini-slings) appear promising yet lack long-term data at this time.
- Of the many articles published on the variety of slings and approaches, few meet the rigorous clinical trial standards needed by physicians to determine which products may be best for their patients.

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- • of interest
- •• of considerable interest

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