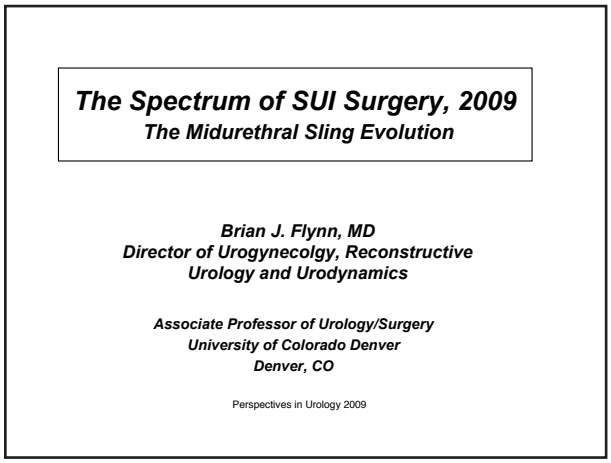
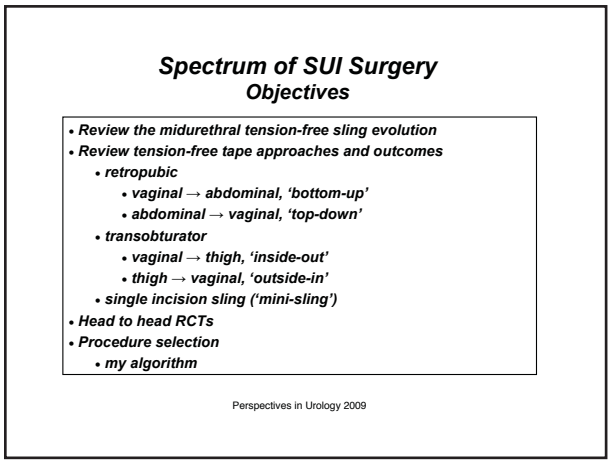
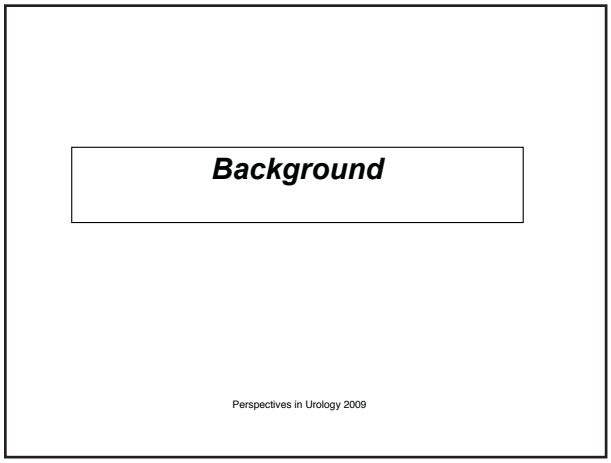
The Spectrum of Stress Incontinence Surgery, 2009

~ Brian J. Flynn, MD







Spectrum of SUI Surgery
Pubovaginal Sling Trends

Out	Trends	In
• Proximal urethra • Tension • Biological materials • Gortex, marlex	⇨	• Mid-urethra • Transobturator • Tension-free systems • Polpropylene mesh

*"Loosely applied mid-urethral slings are the new gold standard for female SUI. Whether these should be composed of synthetic or bio-material can only be determined after comparative randomized controlled trials." **

* Bemelmans, BLH and Chapple, CR: Cur Opin Urol 2003

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Mid-urethral Tapes ('kits')
Timeline

1996	TVT™	• ribbon-like mesh placed via an incision under the mid-urethra, 'bottom-up' Ulmsten, U, et al: Int Urogynecol 1996
2001	SPARC™	• ribbon-like mesh placed via an incision under the mid-urethra 'top-down' Statskin D, 2001
2003	TOT	• transobturator 'outside-in' insertion of polypropylene mesh Delorme, E, et al: Eur Urol 2004
2004	TVT-O ™	• transobturator 'inside-out' insertion of polypropylene mesh De Leval, J: Eur Urol 2004
2006	Mini-sling	• 1.1 x 8 cm polypropylene tape placed vaginally, with 'no exit site'

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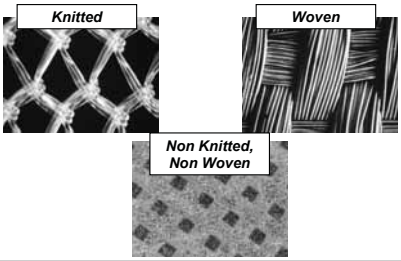
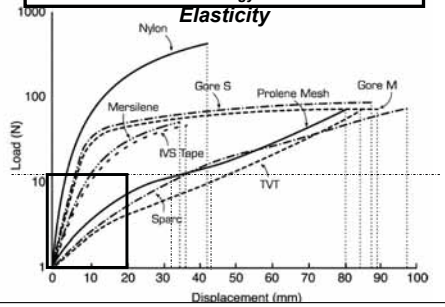
Midurethral Tapes
Are they all the Same?



Alexander 1967 ; Larson et Harrower 1978 Law et Ellis 1991 ; Elek et Conen 1957 ; Neel 1983

Dietz, HP: Mechanical properties of urogyn implant materials. Int Urogynecol 2003

Elasticity



Gynemesh demonstrated low stiffness, easy deformability, and permanent elongation, with the AMS sling showing similar results. Moalli et al. 2008

FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence

10/20/08

>1,000 complications reported in past 3 years from 9 manufacturers

- *obtain specialized training, be aware of risks*
- *be vigilant for potential adverse events (erosion, infection)*
- *watch for perforations from tools*
- *inform patients that mesh implantation is permanent*
- *some complications may require additional surgery that may or may not correct the complication*
- *inform patients about potential for serious complications effecting QOL (dyspareunia, scarring)*
- *provide patients with a written copy of the patient labeling*

"Serious Complications with Mesh Use in PFR and SUI Repair"[1]

http://www.fda/gov/cdrh/safety/102008-surgicalmesh.html

Retropubic Tapes
First Generation TVT

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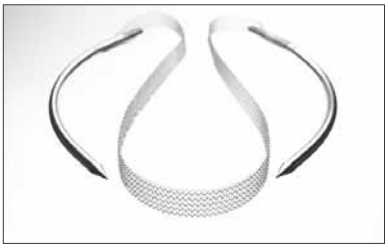
*Tension-Free Vaginal Tape (TVT™)**
Original Device



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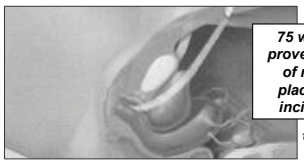
*Tension-Free Vaginal Tape (TVT™)**
Ulmsten's Initial Data, 1996 †



** Gynecare Inc., Summerville, NJ*

75 women with urodynamically proven SUI had a ribbon-like strip of mesh tape (polypropylene) placed through a small vaginal incision under the mid-urethra

† Ulmsten, U, et al: Int Urogynecol 1996

- *Single center, one experienced urogynecologist*
- *Mean operative time was 22 minutes (16-42 min)*
- *All patients discharged < 24 hours, mean convalescence 10 days*
- *Cured 84%, 2-year follow-up*

"Main aims of the TVT operation are to reinforce functional pubourethral ligaments and suburethral vaginal hammock"

Tension-Free Vaginal Tape
Multicenter Scandinavian Trial *

"In order to find out how easy, effective and safe the procedure could be in ordinary gynecologic units."

131 patients with GSUI prospectively underwent primary TVT in six Scandinavian community hospitals

- *OR time was 28 mins, convalescence 2 weeks*
- *Cured 91%, improved 7%, min. f/u 12 months*
- *Complications (6)*
  - *complicated bladder perforation (1)*
  - *wound infection (1)*
  - *urinary retention lasting 3-12 days (3)*
  - *hematoma (2)*
  - *tape rejection (0)*

* *Ulmsten, U, Falconer, C, Johnson, P, et al: Int Urogynecol 1998*

Tension-Free Vaginal Tape
Overview of "Level I Evidence"

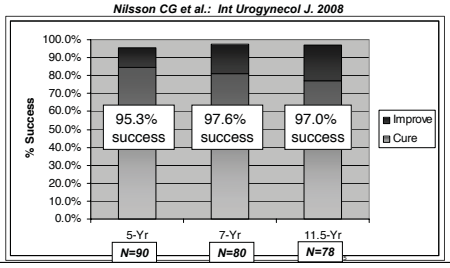
Retropubic Devices	GYNECARE TVT™ Retropubic	SPARC™	Advantage®	Advantage Fit®
Total RCTs	32	7	0	0
Longest Follow-Up in Any Published Study	11.5 years[5]	3 years[9]	N/A	N/A

Retropubic Devices	Align®	Uretex®	Aris®	Lynx®
Total RCTs	0	0	0	0
Longest Follow-Up in Any Published Study	N/A	3 years[10]	N/A	1 year[11]

Tension-Free Vaginal Tape
11-year Data

90 patients with GSUI prospectively underwent TVT in three centers

Nilsson CG et al.: Int Urogynecol J. 2008



Long-term cure rates similar to traditional pubovaginal sling and Burch coplosuspension

Tension-Free Vaginal Tape
"SUI and ISD"

49 women with SUI and ISD underwent TVT *

161 with SUI underwent TVT †*

- *Recurrent SUI 28%*
- *Mixed UI 37%*
- *ISD 11%*

Outcome

- *Few intra- or postoperative complications occurred*
- *Cured 74%, improved 12%*
- *Mean f/u 4 years*

- *Primary 88%*
- *Mixed 81%*
- *Recurrent 84%, low UCP 78%*
- *Mean f/u 16 mos*

* *Rezapour, M et al: Int Urogynecol J Pelvic Floor Dysfunct 2001*

† *Nilsson, CG and Kuuva, N: BJ OBGYN 2001*

Majority of the failures were >70 years of age and had urethral resting pressure of <10 cmH2O and immobile urethra

Spectrum of SUI Surgery
Other Retropubic Devices

- *GYNECARE TVT (ETHICON, INC.) – 11-year data - published*
- *AMS SPARC™ (AMS) – 3 year data - published*
- *Uretex® Self-Anchoring Urethral Support (Bard) – no data*
- *Advantage® Sling System (Boston Scientific) – no data*
- *Sabre™ Bioabsorbable Sling (Mentor) – 6 mo fu data*
  - *multiple reports of extrusion/infection*
- *IVS Tunneler™ (Tyco) – withdrawn from market*
- *9 other brands - no data*

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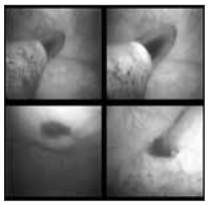
*Trademark

TVT Complication
Polypropylene Bladder Erosion: Retropubic Approach

Bladder perforation is the most common complication of retropubic placement of suburethral tension free vaginal tape for the treatment of SUI

- *Incidence is 2 – 24% reported in published literature **
- *Incidence is as high as 19% in women with prior incontinence surgery †*



** Minaglia S, Klutke C, Klutke, J: Urol 2004*
† Azam J, et al: J Urol 2001

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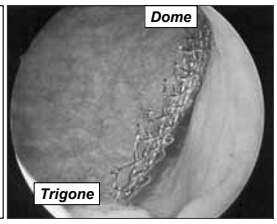
Tension Free Tape-Learning Curve
23 residents with a single senior surgeon

- *mean # of TVT's was 12.1*
- *bladder perforations*
  - *1st 5 TVT's-40.9%*
  - *2nd 5 TVT's-30.7%*
  - *3rd 5 TVT's-25.9%*
- *more perforations with non-dominant hand*
- *less common with older age and increasing weight*
- *37% were missed on cystoscopy by resident*



McLennan and Melick Obstet Gynecol 2005

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Question

Are you aware of any severe bladder, urethral, bowel or vascular injuries in your community

A. *Yes, I have had one personally*
B. *Yes, one of my partners*
C. *Yes, the other group*
D. *Yes, the other specialty*
E. *No*

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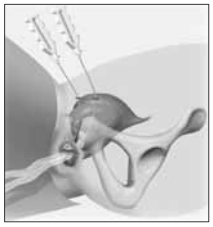
Complications
SPARC™ Sling System *

140 patients underwent SPARC for SUI, hematocrit was measured on POD #1 in the last 57 patients regardless of EBL *

- 4 required transfusion
- 1 patient had a large retropubic hematoma requiring drainage
- 1 bowel perforation required small bowel resection



* Kobashi, KC and Govier, FE: J Urol 2003

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Spectrum of SUI Surgery
Technical Pearls for Sling Placement

Retropubic TVT- Doug Hale, MD

- 1.5 cm incision, full thickness
- push – spread technique
- place catheter guide with tension on catheter
- visualize what is happening
- avoid sulcus – look for "bridge"
- trocar parallel to floor unless proximal sling placement

- perforate perineal membrane
- retract 1cm
- handle parallel to floor
- avoid trocar tip movement
- keep contact with bone
- look for tenting, flash of blood, fluid pooling along trocar
- pull sling to contalateral leg, not straight out
- 70 degree scope mandatory with full bladder

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Transobturator Tapes
Second Generation TVT

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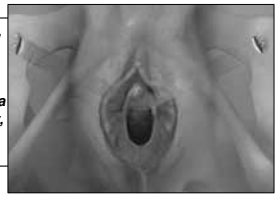
TVT how does it work?
DeLancey's Hammock Hypothesis

In the normal continent female, 'increases in urethral closure pressure during a stress maneuver arise because the urethra is compressed against a hammock-like supporting layer, rather than the urethra being truly intra-abdominal'



* DeLancey, JOL: Am J Obstet Gyencol 1994

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Tension-Free Vaginal Tape
How does it work?

"Urethra is resuspended to correct hypermobility vs. backboard of support during increases in intra-abdominal pressure"

- *20 patients underwent TVT had preop/postop Q-tip angle assessed **
- *Cured 17/20 (85%), improved 2/20 (10%), failed 1/20 (5%)*
- *Mean preoperative Q-tip angle was 42º and postoperative was 32º*
- *11 of the 12 patients with postop Q-tip angle > 30° were cured*
- *The 1 patient that failed had a preop/postop Q-tip angle of 10°*

** Klutke, JJ, at al: Urol 2000*

- *Application of the tape does not elevate the position of the bladder neck at rest, but limits its mobility during valsalva †*

† Atherton, MJ and Stanton, SL: Neurourol Urodyn 1999

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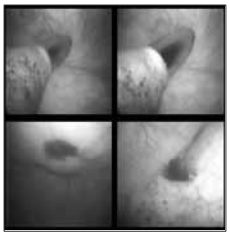
Transobturator Tape
Proposed Advantages

Avoidance of retropubic space

- *Eliminate risk of bladder, bowel, ureteral injury*
- *Avoids scar tissue from prior operations*
- *Less bleeding*
- *Lower risk of retention and de novo urgency*



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PVS Using the Transvaginal Tape Obturator System (TVT-O) For all Types of SUI
1-Year Minimum Follow-up

Flynn BJ: SC AUA 2008

*121 patients with SUI that underwent transobturator inside-out insertion of polypropylene mesh were retrospectively reviewed **

- *64 (53%) patients had prior surgery*
- *Mean follow-up 29.4, 12-46 months*
- *OR time, 26 minutes (range 14-38)*
- *Cured 111 (92%), failed 10 (8%)*

- *Complication (6)*
  - *Bladder perforation (0)*
  - *Mean EBL 33 ml*
  - *De novo urgency (1)*
  - *Urinary retention (3)*
  - *Vaginal erosion (2)*
  - *Urethral injury (1)*

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TVT-Obturator
'Inside-Out'

*107 patients with SUI that underwent transobturator inside-out insertion of polypropylene mesh were retrospectively reviewed **

- *17 patients had prior surgery*
- *1-year minimum follow-up*
- *Mean OR time, 14 minutes (range 7-20)*
- *Cured 91%, improved 9%*

- *Complication (6)*
  - *Bladder perforation (0)*
  - *Hematoma (0)*
  - *De novo urgency (2)*
  - *Urinary retention (3)*
  - *Vaginal erosion (1)*
  - *Urethral erosion (0)*

** De Leval, J: Eur Urol 2004*

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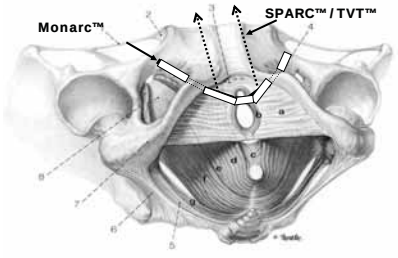
Monarc® Mesh Position



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Reiffenstuhl ,Platzer & Knapstein

Transobturator Tape
Overview of "Level I Evidence"

Transobturator Devices	GYNECARE TVT™ Obturator	Monarc™	Obtryx®	Align TO®
Total RCTs	9	4	0	0
Longest Follow-Up in Any Published Study	3 years[18]	2 years[19]	N/A	N/A

Transobturator Devices	Uretex TO®	Aris TOT®	Desara®*	T-Sling®*
Total RCTs	0	0	0	0
Longest Follow-Up in Any Published Study	N/A	N/A	N/A	N/A

*Desara® and T-Sling ® have multiple placements

Transobturator Tape
Results of RCTs

Liapis A et al.:. Int Urogynecol J. 2008
But I et al.: Int Urogynecol J. 2008

	Liapis (12 mo)[20]		But (4 mos)[21]	
	GYNECARE TVT® Obturator System	AMS Monarc®	GYNECARE TVT™ Obturator	AMS Monarc™
Obj Cure	95%*	94%*	98%	97%
Sub Cure	80%	77%	N/A	N/A
Erosion	N/A	N/A	0%	0%
Bladder Perf	0%	0%	N/A	N/A
Urethral Perf	0%	2%	N/A	N/A
Pt Satisf VAS	N/A	N/A	91%	89%

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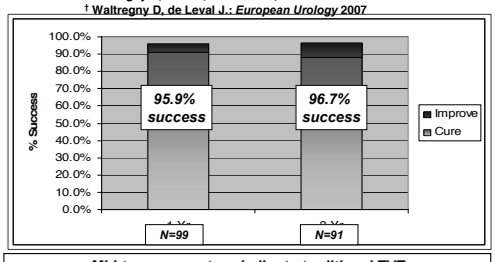
Transobturator Tape
3-year follow-up

Follow-up for 91 of the original 102 patients from the investigator's original data, 3-year minimum follow-up

* Waltregny D, Reul O, Mathantu B, et al.: *J Urol* 2006
† Waltregny D, de Leval J.: *European Urology* 2007



Mid-term cure rates similar to traditional TVT

TOT Complications

Bladder Injury During 'Outside-In' Approach *

TOT using Mentor™ tape in 120 cases
(Uratape in 60, Obtape in 60) with 1-year minimum follow-up

- 13 vaginal wall injuries recognized at the time of surgery
- 3 delayed vaginal wall extrusions
- Three perforations of the urethra and one of the bladder occurred during the learning phase
- In 2 of 3 cases of urethral injury re-intervention was necessary for tape removal when the injury was unrecognized

"It is certainly of importance to put a finger into the midline vaginal incision to protect the urethra from the tunneler. To avoid vaginal perforation, it is also of importance to take care of a good sulcus dissection at the upper lateral vaginal wall. These observations enabled us to continue our series without the need to perform cystoscopy."

* Roumegue`re T, et al: EU 2005

TVT-Obturator

'Inside-Out'

136 patients with SUI treated with TVT-R were randomized against 131 patients treated with TVT-O*

- Short-term cure:
  - TVT = 98.5%
  - TVT-O = 95.4%

	TVT	TVT Obturator
Bladder Perforation	1	0
Vaginal Perforation	2	3
Hematoma	1	0
Pain (thigh/groin)	2 (1.5%)	21 (16%)

*Trademark

Nilsson CG et al. *Int Urogynecol J.* 2006

Walters Spectrum of SUI Surgery

Technical Pearls for Sling Placement

TVT-O Mark Walters, MD

- know the obturator anatomy
- high stirrups with buttock to end of table
  - especially in obese women
- hydrodissection
- 2 cm mid-urethral vaginal incision
- limited dissect. to pubic ramus
  - little bigger than TVT
- exit at level of clitoris lateral to the labia major, below the adductor longus tendon

- empty bladder
- proper alignment of helix
- then bilat passage
- cystoscopy
  - 1 bladder perf in 1150 cases)
- tension over Kelly clamp loosely
  - no gap to the urethra
  - tighter than TVT
  - looser than TVT-Secur

Single-Incision Slings or 'Mini-Sling'

Third Generation TVT

Spectrum of SUI Surgery
What we Need in a 3rd Generation Sling

Simplify the procedure

- simpler and less-invasive techniques
  - minimal passage through tissues
  - less anesthesia
  - further reduce procedure time
  - eliminate external incisions

Decrease morbidity and convalescence

- maximum safety
  - Less material left behind in the patient
  - Eliminate mesh lateral to obturator
- potential for quicker return to normal activities for the patient

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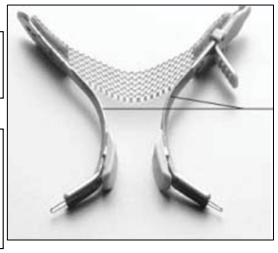
Tension-Free Vaginal Tape Secur (TVT-S™)
Proposed Advantages

Simple, outpatient procedure done under local anesthesia

Sling Design

- dimensions 8 cm x 1.1 cm
- laser cut
- no exit point
- unique fixation technique



Procedure Advantages

- less dissection and pain
- less bleeding
- no risk of bowel, nerve ureteral injury
- decreased risk of urethral obstruction
- ability to do a cough test

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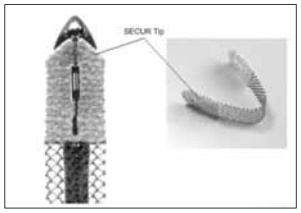
Tension-Free Vaginal Tape Secur (TVT-S™)
Absorbable Fixation Tips



Fixation Tips

- secures sling without anchors
- fleece absorbed within 90 days
- fixation is then provided by the mesh
- similar material used in dental implants

- 2 cm absorbable fixation tips of fleece-like material sandwich the mesh at the tips
- absorbable tips are made of Vicryl (polyglactin 910) suture yarn and PDS (polydioannone)

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Tension-Free Vaginal Tape Secur (TVT-S™)
Tape Location

Same kit may be used to place the tape in either position

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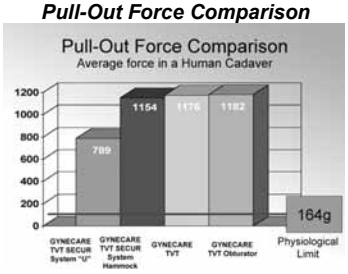
Tension-Free Vaginal Tape Secur (TVT-S™)
Pull-Out Force Comparison



Pull-Out force evaluated in the GU diaphragm and obturator membrane of a human cadaver

Perspectives in Urology 2009

AUA 2008 Abstract 1566: UNFAVORABLE IMMEDIATE OUTCOME OF THE TVT SECUR SLING IN TWENTY CONSECUTIVE WOMEN WITH SUI
Fabio Baracat, et al Sao Paulo, Brazil*

20 patients underwent TVT-secur in the 'hammock' configuration into the obturator internus muscle, in the same tension free process as the classic TVT

- ***mean preoperative VLPP, 76.3 cm H2O***
  - ***did not differ between the groups (cured, improved and failed)***
  - ***40% (8 cases) dry, 20% (4 cases) improved, 40% (8 cases) failed***
- ***cure rate was 40% at 3 months***
- ***blood loss was minimal and no bladder perforation occurred***
- ***only three patients (15%) needed analgesics***

TVT SECUR in the hammock configuration tensioned as classic TVT leads to poor outcome

Perspectives in Urology 2009

2009 AUGS Abstract: Efficacy and complications of TVT-Secur in the management of stress urinary incontinence
Terlecki RP and Flynn BJ et al, Denver, CO

55 women with all types of SUI underwent the TVT-secur in the 'U' configuration tensioned with the mesh abutting the urethra

- ***concomitant pelvic procedure (n = 21)***
- ***exclusion criteria***
  - ***neurovesical dysfunction (n =2)***
- ***prior incontinence surgery, 15 (27%), 9 PVS, 6 suspensions***
- ***prior hysterectomy, 34 (62%)***
- ***pre-op pad usage***
  - ***mean daily pad use, 2 (1-4)***
  - ***mean 24-hour pad weight, 65 (3-110) gms***
- ***severe ISD (VLPP < 60 cm H2O), 14 (26%) patients***
- ***BMI was 29.6 kg/m²***

Flynn BJ et al: AUGS 2009

Perspectives in Urology 2009

2009 AUGS Abstract: Efficacy and complications of TVT-Secur in the management of stress urinary incontinence
Terlecki RP and Flynn BJ et al, Denver, CO

Anesthesia

- ***all cases performed IV sedation/local anesthetic***
  - ***Propofol 175 µg***
  - ***Midazolam 0.51 mg***
  - ***Fentanyl 57 µg***
  - ***50/50 mix of 1% lidocaine/0.25% bupivicaine (40 ml)***

Surgical Approach

- ***TVT-s inserted in the 'U' configuration***
- ***intra-operative cough test used to adjust sling tension***
- ***cystoscopy performed in all cases to r/o urinary tract injury***

Flynn BJ et al: AUGS 2009

Perspectives in Urology 2009

2009 AUGS Abstract: Efficacy and complications of TVT-Secur in the management of stress urinary incontinence

Terlecki RP and Flynn BJ et al, Denver, CO

Convalescence

- *mean operative time 34 minutes*
- *all patients discharged same day without catheter*
- *all patients returned to daily activity in < 7 days*

Complications

- *no to urethra, bladder, bowel, or neural injury*
- *0 vaginal mesh extrusion*

Flynn BJ et al: AUGS 2009

Perspectives in Urology 2009

2009 AUGS Abstract: Efficacy and complications of TVT-Secur in the management of stress urinary incontinence

Terlecki RP and Flynn BJ et al, Denver, CO

TVT-S

- *34 of 55 (62%) patients*
- *mean f/u 5 (1-13) months*
- *EBL = 16 ml*
- *28 of 34 (82%) patients cured*
  - *25 patients, 0 pads*
  - *3 patients, 1 ppd*
- *6 of 34 patients failed*
- *1 case (2.9%) of obstruction*
  - *sling lysis at 6 weeks*
  - *now voiding*
  - *continence maintained*

TVT-S + Concomitant Procedure

- *21 of 55 (38%) patients*
- *mean f/u 5 (1-13) months*
- *POP surgery in 16*
- *19 of 21 (90%) patients cured*
  - *25 patients, 0 pads*
  - *3 patients, 1 ppd*
- *2 of 21 patients failed*
- *4 cases (19%) of obstruction*
  - *sling lysis in 4*
  - *now voiding*
  - *continence maintained*

Flynn BJ et al: AUGS 2009

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MiniArc Single-Incision Sling System™
Proposed Advantages

Simple, outpatient procedure done under local anesthesia

Kit Design

- *dimensions 8.5 cm x 1.1 cm*
- *slim Needle Design*
  - *2.3mm diameter*
- *ergonomic Handle*
- *blunt, bladeless tip*

Procedure Advantages

- *single, small vaginal incision*
- *no mesh beyond obturator*
- *same proven materials and trajectory as Monarc*
- *easy to Perform*

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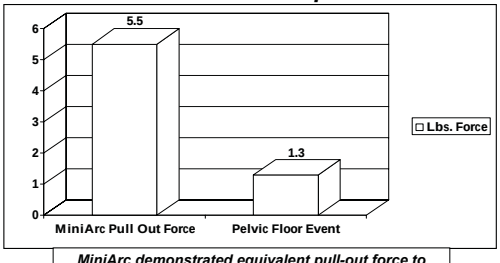
MiniArc Single-Incision Sling System™
Pull-Out Force Comparison



MiniArc demonstrated equivalent pull-out force to Monarc (AMS data on file) in cadavers

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ICS 2009: MiniArc Multicenter Prospective Single-Arm Trial
Michael Kennelly, Dirk DeRidder and Steve Siegel, ICS 2008

151 patients underwent MiniArc Sling

- ***demographics***
  - ***mean age 51 (32-79) years***
  - ***mean BMI 27.6 kg/m²***
  - ***mean parity = 2***
- ***procedural***
  - ***44% general anesthesia***
  - ***56% local anesthesia***

- ***mean pain score at discharge***
  - ***0.78 ± 1.23***
- ***estimated blood loss***
  - ***Median = 25mL***
- ***mean length of stay***
  - ***Median = 2.8 hours***
- ***intra-operative complication***
  - ***1 (0.7%) vaginal wall perf***

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ICS 2009: MiniArc Multicenter Prospective Single-Arm Trial
Michael Kennelly, Dirk DeRidder and Steve Siegel, ICS 2008

6 Week Follow-up Results

N=149 Subjects	
Median Pain Score	***0***
Mean Pain Score	***0.3 ± 0.9***
Recommend to a friend	***95.3%***
Cured/improved	***94.7%***
Not improved	***5.3%***

6 month Efficacy

- ***CST negative in 94% (68/72)***
- ***Mean 1-hr pad weight test***
  - ***baseline = 26.5 ± 38.1 gm***
  - ***6 months = 5.2 ± 28.5 gm (n=80)***

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Single-Incision (Mini) Sling Tensioning Recommendations

- ***mini-sling tensioning is <u>tighter</u> than retropubic or TOT procedures***
- ***mesh should lie flat against the urethra***
  - ***minimal-no space between the urethra and sling***
- ***over tensioning is possible after inserting the second tip***
- ***tension both sides together***
- ***CST is vital for success***
- ***<u>MinArc</u>***
  - ***<u>only push forward</u> as to not disengage needle from mesh***
- ***TVT-s***
  - ***easier to push in further than to try to pull out***

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Single-Incision (Mini) Sling Overview of "Level I Evidence"

Single-Incision Devices	GYNECARE TVT SECUR™	MiniArc™	Contasure	Solyx
Total RCTs	0	0	0	0
Longest Follow-Up in Any Published Study	1 year[32]	6 months[33]	N/A	N/A

Single-Incision Devices	Ajust	Prefyx-PPS™*	Minitape®	Needless™
Total RCTs	0	0	0	0
Longest Follow-Up in Any Published Study	N/A	N/A	N/A	N/A

Tension-Free Vaginal Tape Secur (TVT-S™)
IUGA 2007

Author(s)	# Pts	Mean f/u	Subjective Cure	Failed/ Worse	Objective Cure	Complications
Marsh et al, UK	40 (H-U n/a)	6 wk	74% dry 12% imp	14% no Δ		1 "buttonhole" 2 vd Dysfcn 1 exp/1 pain
Shaare-Zedek, Israel	150	n/a	97%	3% no Δ		5 unintended device removal
Saltz et al, USA	77 (27-U/50-H)	6 wk	68.8% dry 13% imp	3% worse		2.6% vd Dysfcn 1 pain
Karram et al, USA	60 (29-U/31-H)	6 wk	86.7% >50% imp on VAS	3% worse	-cst 75% +cst 25%	1 bladder perf 3 de novo OAB 1 exp
Debodinance et al, France	40 (all H)	8 wk	76.9% dry 15.4 imp	7.7% no Δ		5 vd Dysfcn 1 exp Denovo OAB/UUI-20%
Totals (not a meta analysis)	**410**	**6.6 wk**	**85.4%**	**8.5% no Δ 6% worse**	**-cst 77%**	

Int Urogynecol J. :18 (Suppl): 2007

Single-Incision (Mini) Sling
Summary

Advantages

- small vaginal incision, no exit point
- quick, safe, minimal dissection
- done under local anesthesia

Early observations

- tensioned differently than traditional TVT
  - mesh is in direct contact with urethra
- use with caution in concomitant POP cases
- technically demanding procedure
  - patient selection
  - CST vital for success

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Flynn Spectrum of SUI Surgery
Technical Pearls for Sling Placement

Mini-Sling

- minimize dissection
- do not perforate endopelvic fascia or obturator membrane when dissecting
- mini-sling tensioning is <u>tighter</u> than retropubic or TOT procedures
- mesh should lie flat against the urethra
  - minimal-no space between the urethra and sling
- over tensioning is possible if particular attention is not paid while inserting the second tip

- cough-test is vital for success

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Head to Head RCTs

Perspectives in Urology 2009

Spectrum of SUI Surgery

RCT TVT® v. Monarc® in Patients with SUI

Barber, M. et al.: OB Gyn 2008

- N=170 women from 3 centers with USUI
- Mean f/u 18.2 months
- Exclusion
  - Detrusor overactivity
  - Previous sling surgery

Conclusion

"…Monarc TOT is not inferior to TVT for the treatment of stress urinary incontinence and results in less bladder perforations…"

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Spectrum of SUI Surgery

RCT TVT® v. Monarc® in Patients with SUI

Barry et al.: Int Urogynecol J 2007

- Australian multi-center randomized prospective study
- 140 women with 3 month f/u

Conclusion

"…Transobturator tape [Monarc] appears to be as effective as the retro-pubic tape [TVT] in the short term, with a reduction in the risk of intra-operative bladder injury, shorter operating time, decreased blood loss and quicker return to normal activities…"

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Spectrum of SUI Surgery

RCT TVT® v. Monarc® in Patients with SUI

- N=273, 7 centers in Finland
- Cure = negative cough stress test
  - 98% in TVT v. 95% in TOT
- Return of normal voiding = PVR<100
  - 6 hours in TVT v. 9 hours in TOT
- Groin pain hospital stay was greater in TOT

Laurikainen et al; Ob Gyn 2007

TOT was not found to be inferior to TVT with respect to efficacy but had more groin pain

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Spectrum of SUI Surgery

Retrospective Comparison of PVS, TVT and TOT in ISD

- 273 women with ISD
  - VLPP < 60 cm H2O or
  - MUCP <20 cm H20
- Follow up at 24 months
- Cure = subjective absence of sx & -CST
  - PVS= 87%
  - TVT=87%
  - TOT= 35%

Jeon et al AJOG 2008

- N=164, 2 hospitals
- Cure = absence of SUI on UDS
- Secondary outcomes
  - Sx stress
  - Surgical complications
  - QOL questionnaires
- Urodynamic testing at 6 months
  - TVT-21% leakage (79% cure)
  - TOT-45% leakage (55% cure)

Schierlitz et al. Ob-Gyn 2008

TOT was found to be inferior to PVS and TVT with respect to efficacy in patients with ISD

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Midurethral Tape Debate
TOT vs. TVT in Patients with Low MUPP

An outcome analysis was performed in 145 women that underwent sling for SUI with a MUCP < 42 cm H2O (Monarc = 85; TVT = 60)

- *Baseline characteristics were similar*
- *Relative risk of postoperative SUI 3 months after surgery was 2.85 in all patients when Monarc was compared to TVT*
- *RR was 0.56 if MUCP > 42 cm H2O*
- *RR was 5.89 if MUCP < 42 Cm H20*

The cure rate after TOT is inferior to TVT in women with ISD

** Miller JJ, Sand PK et al, Obstet Gynecol 2006*

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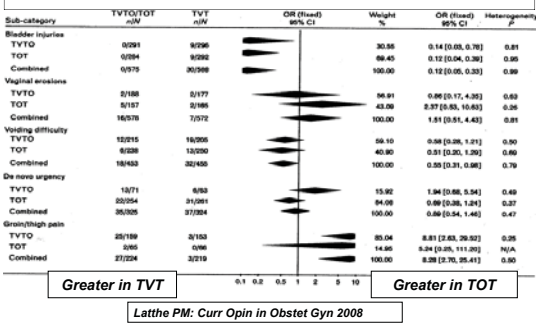
Spectrum of SUI Surgery
Risk of Complications with TVT vs TOT



Latthe PM: Curr Opin in Obstet Gyn 2008

What I do and Why

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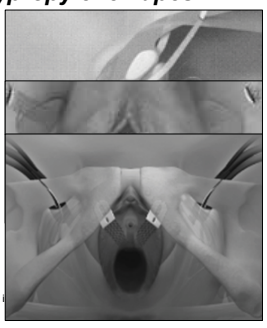
Minimally Invasive Sling Surgery
Evolution of Polypropylene Tapes

- *First generation*
  - *retropubic placement*
  - *effective at 7 years f/u*
  - *uncommon, but serious complication (bladder, bowel, vascular)*
- *Second generation*
  - *transobturator placement*
  - *effective at 2 years f/u*
  - *rare, complication of thigh pain*
- *Third generation*
  - *mini-sling (8 cm)*
  - *minimal on efficacy*
  - *? no complications*



Spectrum of SUI Surgery
April 2003- July 2009

- Retropubic tapes
  - n = 72 (16%)
- TO tapes
  - n = 190 (42%)
- Mini-slings
  - n = 119 (26.4%)
- Biological Slings
  - Autografts, 33 (7.3%)
  - Allografts, 27 (6%)
  - Xenografts, 0
- AUS, 9 (2%)

Totals

- Synthetics, 390 (86.7%)
- Biologicals, 60 (13.3%)

Retropubic Tape 2001

↓

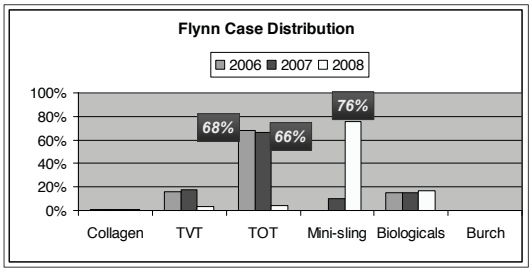
Transobturator Tape 2004

↓

Mini-sling 2007

Flynn Spectrum of SUI Surgery
2006 - 2008

Primary procedure for SUI in 2008 is Mini-Sling replacing TOT 2006-07



Institutional Sling Extrusion Data
April 2003-Present

GU tract erosion data of mesh, silicone and biologicals

- Vaginal wall extrusion/pain
  - retropubic tape 1 of 72 (1.4%)
  - TVT-O, 4 of 190 (2.1%)
  - TVT-S, 1 of 119 (0.8%)
  - Biological PVS, 0 of 60
  - AUS, 0 of 9
- Urinary tract erosion
  - retropubic tape 1 of 72 (1.4%)
  - TVT-O, 1 of 190 (0.5%)
  - TVT-S, 0 of 119
  - Biological PVS, 0 of 60
  - AUS, 0 of 9

Perspectives in Urology 2009

2010 SUFU Abstract: MANAGEMENT OF RECURRENT VAGINAL WALL EXTRUSIONS AND URINARY TRACT EROSIONS AFTER INCONTINENCE AND PROLAPSE SURGERY

Flynn BJ et al, Denver, CO

Retrospective review in 82 patients that underwent explantation of an eroded device due to recurrent vaginal wall extrusions and/or urinary tract erosions

- removal of exposed/eroded sling material, sutures and prolapse mesh by a single surgeon at CU since 2003
- Type of material

· Suspension sutures/plegets	n = 5 (5.9%)
· Xenografts	n = 10 (11.8%)
· Retropubic tapes	n = 15 (18.3%)
· TOT	n = 29 (35.6%)
· Mini-sling	n = 2 (2.4%)
· Prolapse kits	n = 17 (20.7%)
· ASC	n = 4 (4.9%)

Flynn BJ et al: SCAUA 2007

~ Brian J. Flynn, MD