Surgery For Stress Incontinence: Choosing A Procedure In 2004

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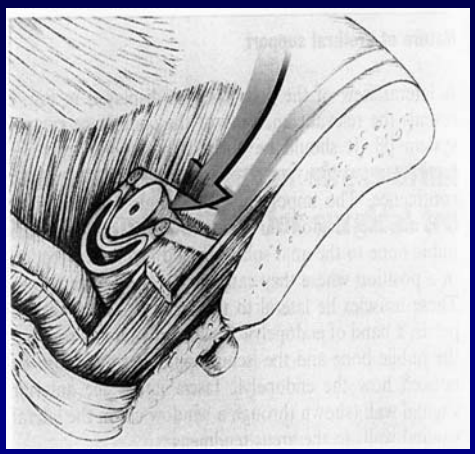
How does the urethra stayed closed during increases in intra-abdominal pressure?

- With rises in intra-abdominal pressure, the urethra is compressed against the supporting structures which act like a backboard
- Stability of the supporting structures (not position or height) determines continence
  - When supporting structures are unstable, occlusive action is lost



DeLancey World J. Urol., 15:268, 1997

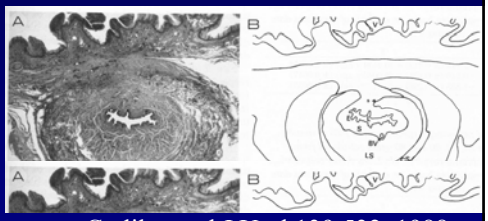
Integral Theory

Petros and Ulmstem, 1990

- Proposes that control of the urethra closure is mainly the interplay of 3 structures
  - pubourethral ligaments
  - suburethral vaginal hammock
  - pubococcygeus muscle

Intrinsic Urethral Sphincter

- Midurethra made up of several layers:
  - Mucosal (epithelial) layer
  - Submucosa
  - Inner longitudinal smooth muscle
  - Outer circular smooth muscle
  - Some studies suggest a middle transverse smooth muscle layer
  - Striated muscle
    - All muscle layers are sparse toward the dorsal side and thicker ventrally



Carlile, et al J Urol 139:532, 1988

Stress Continence

- Dependent upon:

1. Stability of supporting structures
   - Fascial strength
   - Intact attachments
   - Contribution of levators
2. Intrinsic function of bladder neck and urethra
3. ? contribution of compensatory mechanisms from striated sphincter mechanism

Stress Incontinence Treatments

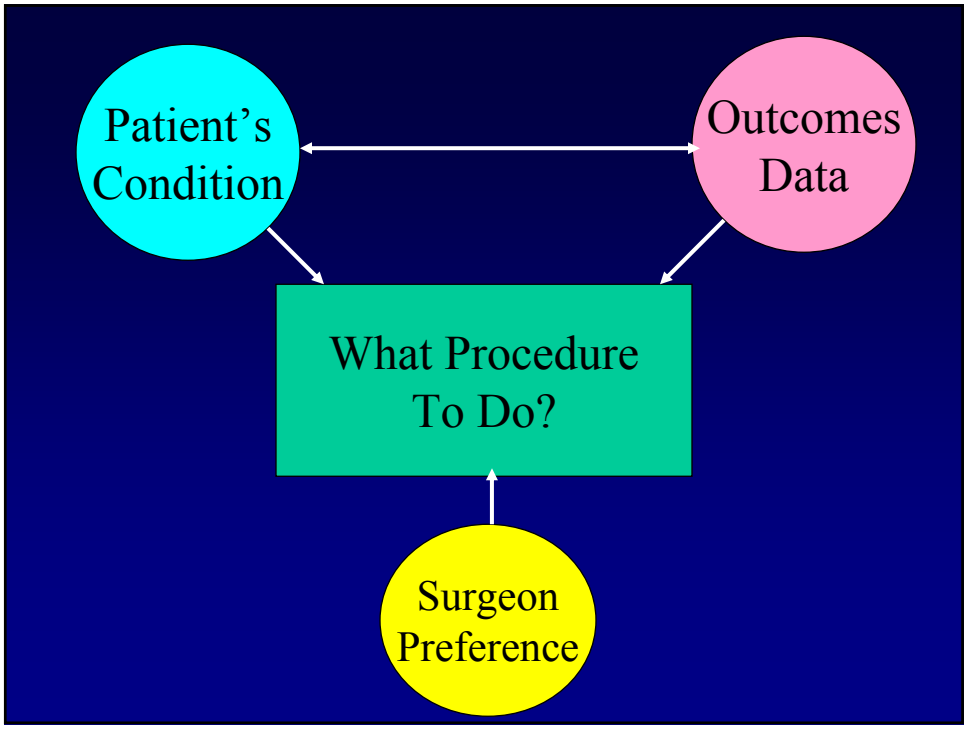
- Behavioral Modification
- Pelvic floor exercises
- Medications
- Devices
- Urethral bulking agents
- Surgery
- Artificial urinary sphincter

Surgery for Stress Incontinence

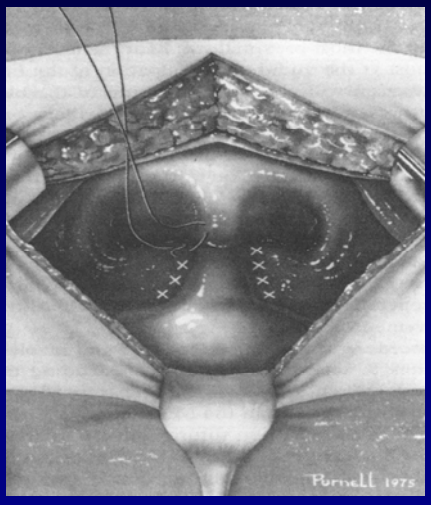
- Suspensions
  - Reinforce and strengthen existing supporting structures
    - "Fix the backboard"
- Slings
  - Use new structures to create a support system
    - "Replace the backboard"
  - May also compress & coapt urethra independent of supporting

AUA Female Stress Urinary Incontinence Clinical Guidelines, 1997

- Mean cure/dry (cure/dry/improved) rates at 48+ months:
  - Retropubic suspensions - 84% (90%)
  - Sling procedures - 83% (87%)
  - Transvaginal suspensions - 67% (82%)
  - Anterior repairs - 61% (73%)
  - Reported rates for slings based on use of autologous fascia and synthetic material predominately on patients with type 3 SUI



Retropubic Suspensions



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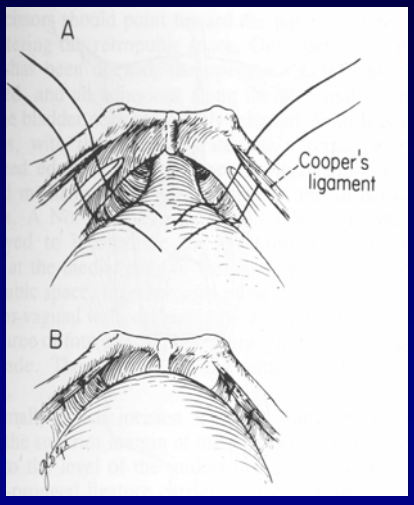


Burch

Retropubic Suspension Options

- Open
- Laparoscopic
  - Described in 1991 by Vancaillie and Schuessler
  - Many variations of technique
  - Few good comparative studies
  - Long-term randomized studies lacking
  - Decreased popularity with advent of TVT

Sling Options

- Type of material
- Position of sling
- Length of sling
- Operative approach

Sling Options

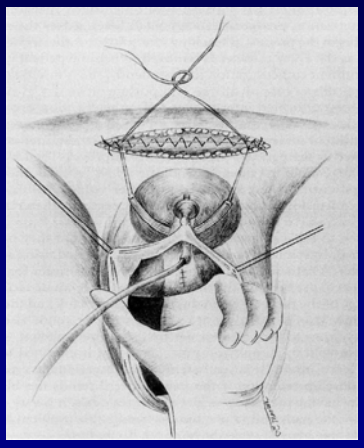
- Pubovaginal sling (bladder neck)
  - Autologous fascia
  - Allograft / Xenograft
  - Synthetic
- Midurethral synthetic sling
  - TVT
  - SPARC, Uretex
  - "Homemade versions", PVT
- Transvaginal bone anchored sling

Sling Surgery
Conditions Which May Effect Procedure

- Urethral mobility
- Urodynamic parameters (ALPP)
- Occult SUI with prolapse repair
- Complex cases
  - Failed prior surgery
  - Prior eroded synthetic
  - With urethral diverticulectomy or VVF repair

"Traditional" Pubovaginal Sling

- Sling placed at the level of the bladder neck
- Sling extends into the retropubic space on both sides
- Can be done with autologous fascia, allograft, xenograft or synthetic material



Pubovaginal Sling

Chaikin, et. al., J. Urol. 160: 1312, 1998

	1 yr.	3 yrs.	5yrs.	> 10 yrs.
No. pts	250	103	47	20
% cured SUI	94	94	95	95
% de novo UUI	3	5	5	0
% persistent UUI	23	26	31	41

- Overall 73% cured and 19% improved

Pubovaginal Sling

Morgan, et. al., J. Urol. 163: 1845, 2000

	2 yr.	3 yrs.	4yrs.	5+ yrs.
No. pts	247	178	144	88
% cured SUI	93	91	88	85

% de novo UUI	7
% persistent UUI	26

- 92% "highly satisfied" based on UDI-6

Pubovaginal Sling

- In order to reduce operative time, recovery time and overall morbidity modification of classic pubovaginal sling evolved
  - Eliminate fascial harvest
  - Eliminate suprapubic incision

Cadaveric Fascia Lata

- Processing may effect strength and durability
  - Solvent, dehydrated, gamma irradiated
    - e.g. Tutoplast®, Mentor Corp
  - Freeze dried
    - e.g. FasLata®, CR Bard Inc
    - e.g. fascia obtained from tissue banks using American Association of Tissue Banks process
- Lermer, et al Neurourol Urodynam 1999
  - Tensile strength, stiffness and intra-tissue consistency:
    - solvent dehydrated fascia similar to autologous rectus fascia
    - freeze-dried fascia significantly lower
- *No clinical trials comparing outcomes of different types of allograft fascia*

Is Allograft Fascia Equivalent To Autologous Fascia?

Integrity of Fascial Slings

Fitzgerald, et al

Cadaveric

BJU 84:785,1999

- Re-op on 8 failures
  - 1 - intact
  - 2 - only remnants were short (1 cm) strands
  - 5 - no remnants of fascial graft
  - "Autolysis may be a significant problem"

Autologous Rectus

Am J Obstet Gynecol 183:964, 2000

- Re-op on 5 patients
  - Sling viable in all
  - Fibroblasts with remodeling along lines of stress at 3,5,8,17 wks.
  - Increased vascularity at 4 yrs
  - "Scar-like tissue seems to function clinically in its new role"

Pubovaginal Sling
Autologous vs. Cadaveric Fascia Lata

Brown & Govier, J. Urol. 164:1633, 2000

	Cadaveric	Autologous
No. pts.	112	46
Responders*	104 (86%)	30 (65%)
Mean follow-p (months)	12	44
Cure SUI*	85%	90%
Cure incontinence*	74%	73%
Improved continence*	19%	27%
Failed*	7%	0
Mean operative time (min)	82	129

* Questionnaire-based results

Pubovaginal Sling
Autologous vs. Cadaveric Fascia Lata
O'Rielly & Govier, J. Urol. 167:1356, 2002

- Intermediate term failures of pubovaginal slings using cadaveric fascia
  - Of 121 patient previously reported an additional 8 failed at 4-13 months (mean 6.5)
  - Similar later failures not reported in autologous fascia group

Study	Type Fascia	Mean F/U	Cured	Improved	Rec
Flynn & Yap 2002	Tissue bank F-D, γ Irr.	29 months	71%	13%*	Pro
Elliott & Boone 2000	Tutoplast	15 months	77%	15%	Pro
Walsh, et al 2002	Tissue bank γ Irr., lyophilized	13 months	94%**		Pro
Huang, et al 2001	Tutoplast	9.2 months	72%***		Con

* Cured and improved = 77% and 13% with autologous (mean f/u 44 months) Patient satisfaction favored autologous (91% vs. 78%, p = 0.05)

** VAS mean subjective improvement 85%; Mean satisfaction 69%: 81% would undergo again

*** Same surgeon using autologous, 94% cured or improved at mean f/u of 17.5 months

Allograft Fascia Bottom Line

- Reduced operative time
- Reduced recovery time
- Short term outcomes similar to autologous fascia
- Several studies suggest late failures
  - Histological studies may be a cause for concern for durability
- Appropriate for "select cases", but lack of long-term data should be explained to the patient

Contemporary Synthetic Pubovaginal Sling

- Shah, et al J Urol 2003;170:849
- Broad-based **polypropylene** sling at BN using SP bone anchors
  - Retrospective review of 58 pts. – 49 available for full f/u mean **59 months** (29-77)
  - 86% cure, 4% significant improvement
  - 76% pad free, 8% rare pad
  - No infection / erosion
  - 4% retention requiring takedown

Other Sling Materials

- Allograft dermis – little short term data
  - Alloderm
  - Repliform
  - etc

- Xenografts – limited clinical data
  - Bovine pericardium
  - Porcine dermis – Pelvicol, Dermatrix
  - Porcine small intestine submucosa – SIS

Xenografts

Peer Reviewed Literature

- Pelvicol - Barrington et al BJU, 2002
  - 40 women
  - Mid urethral sling
    - (2x10-12 cm)
  - Mean f/u 12 months
    - Range 6-18 months
  - 85% "sustained cure"
  - 3 required take-down
  - 78% would have again
- STRATASIS - Colvert et al J Urol, 2002
  - 20 children (13 F, 7 M)
  - Multicenter
  - Neurogenic VD
  - Suprapubic approach
  - Mean f/u 13 months
    - Range 9-26
  - 70% continent
    - 85% F
    - 43% M

Pelvicol vs. TVT

Arunkalaivanan and Barrington, Int Urogynecol J, 2003

- 142 women with SUI randomized to TVT or Pelvicol midurethral sling
  - No anatomic characteristics given
- Mean f/u for both groups = 12 months (6-24)
- Complete cure in 74% vs. 76%
- Additional significant improvement in 10% vs. 14%
- Patient determined continence rates 85% vs. 89%
- 4% vs. 6% considered themselves SUI failures
- *Essentially no differences in outcomes*

Porcine SIS

Rutner et al Urology 2003;62:805

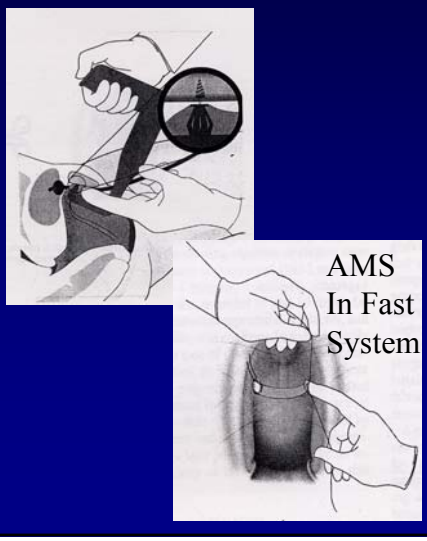
- 152 women, median f/u 2.3 years (4-48 months)
- SIS with transvaginal bone anchors
- 93.4% dry, 2% improved, 4.6% failed
  - 5/7 failures within first 4 months
- 2 redo's – no gross SIS, minimal fragments microscopically

Xenograft Bottom Line

- Peer-reviewed literature suggests that a Pelvicol midurethral sling has similar efficacy to TVT at 1 year
  - 2 articles, same author
  - No results beyond mean f/u of 1 year and max. f/u of 24 months
- No peer-reviewed literature on other products

Transvaginal Bone Anchored Sling

- Procedure done completely transvaginally
- Bone anchors into pubic bone
- Several systems available
- Utilize allographic or synthetic material



Transvaginal Bone Anchored Sling

- Madjar, et al Urology 55:3, 2000
  - 62 patients, gelatin-coated Dacron sling (Infast system)
  - 88.7% cure in 62 women with mean f/u of 12.5 months
- Carbone, et al J Urol 165:1605, 2001
  - 154 patients, cadaveric fascia
  - 38% failure at mean f/u 10.6 months
  - Procedure abandoned - technique vs. material
- Schostak, et al Gynecol Obstet Invest 54:154, 2002
  - 26 patients, 1cm Dacron sling (Infast or Intact systems)
  - 62% cured, 22% improved at mean f/u 11.4 months
  - 54% erosion rate: 50% reoperated
  - 65% dissatisfied or very dissatisfied

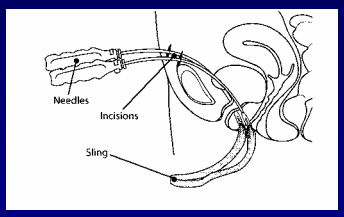
Transvaginal Bone Anchored Sling

- Chon, et al ICS 2003
  - CATS (cadaveric fascia), questionnaire study
  - 328 women with min 6 month f/u
  - 61% of patients $\geq$ 80% satisfied
  - 70% would have surgery again
  - 26% had < 50% improvement in continence
    - 8% stress
    - 13% urge
    - 5% unsure

Midurethral Synthetic Sling

Midurethral Polypropylene Slings

TVT

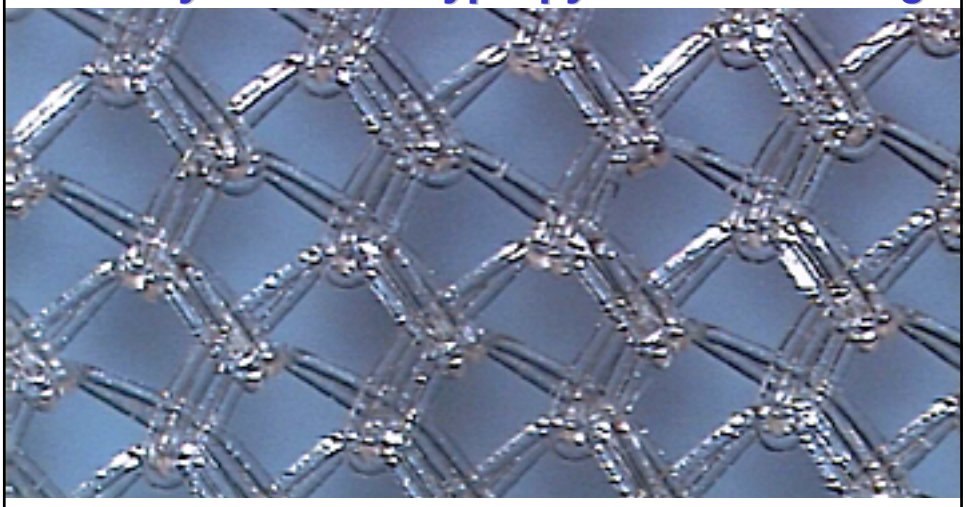


SPARC

Artificial Graft Material

NAME	COMPOSITION
Mersilene	polyethlene terephthalate
Marlex	polypropylene
Prolene	polypropylene (Hernia mesh)
Prolene Soft	loosely woven (Gynemesh)
Teflon	polytetrafluoroethylene (PTFE)
Gore-tex	expanded PTFE
Silastic	silicone rubber + mersilene

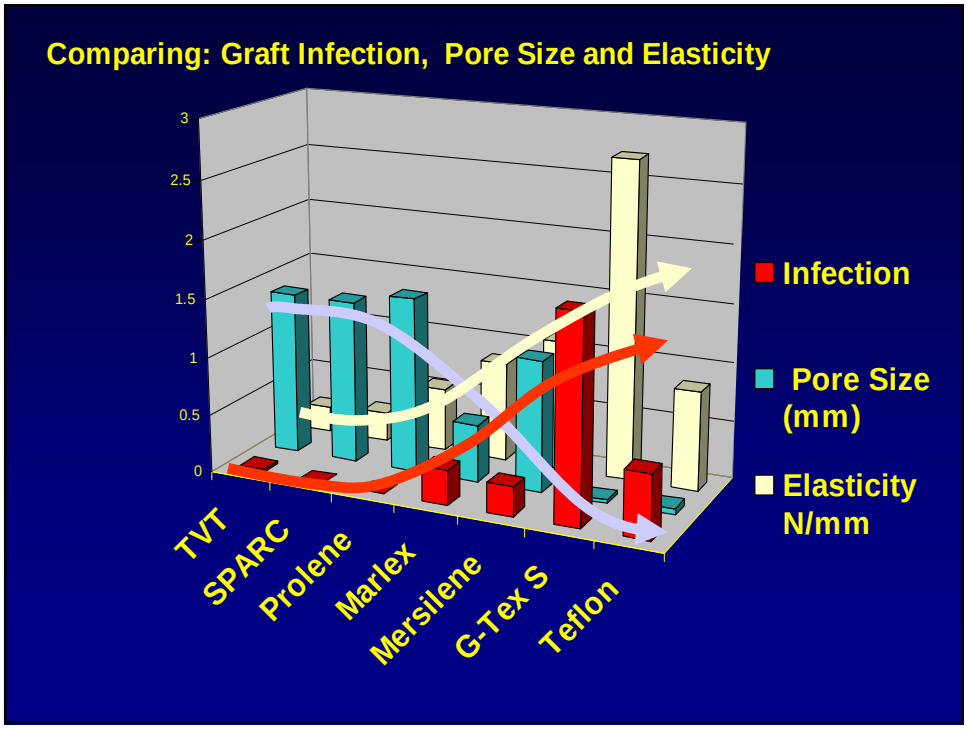
Loosely Woven Polypropylene Mesh Sling



inert material - large pore size

minimizes chance of colonization or infection

facilitates vascular in-growth and tissue in-growth



Tension-Free Vaginal Tape

- TVT introduced in 1995
  - Prolene tape
  - Over 500,000 cases done world-wide
- Based on Integral theory set forth by Petros and Ulmsten
  - Proposes that control of the urethra closure is mainly the interplay of 3 structures
    - pubourethral ligaments
    - suburethral vaginal hammock
    - pubococcygeus muscle

TVT Results

- Large number of *prospective* studies in the literature by multiple authors from different countries show that at 1,2,3,4 and 5 years:
  - Cure 84-88%
  - Significant improvement 7-10%
  - Failure ~ 5-8%
- Multicenter randomized trial of TVT vs Burch* with strict criteria for cure (neg 1 hour pad test)
  - At 2 years 63% cure for TVT vs 51% for Burch (ND)

* Ward and Hilton Am J Ob Gyn 2004; 190, 324

TVT Indications

- Literature supports use in
  - Obese patients
  - Elderly
  - Failed prior surgery
  - Low ALPP or MUCP with hypermobility
  - Concurrent prolapse repair

TVT Outcomes

- Decreased success with lower MUCP
  - 74% vs. 85% cure - Rezapoor 2001
  - Similar postop satisfaction but worse pad test when MUCP < 20 - Kulseng-Hanssen, 2001
  - No mention of mobility

TVT Outcomes

- Urethral mobility not MUCP predictive of outcome – Fritel, 2002
  - Urethral mobility determined on lateral cystogram
  - Mean f/u 9 months
  - Objective success based on urethral mobility (p=0.023)
    - > 60° - 97%
    - 30-60° - 86%
    - < 30° - 70%
  - Strong association of urethral mobility and previous surgical failure
  - No difference in success based on MUCP (p=0.65)
    - < 20 cmH2O - 80%
    - > 20 cmH2O - 85%

SPARC Outcomes

- Multiple abstracts showing similar efficacy as TVT at 1-2 years
- French multicenter trial
  (Deval et al Eur Urol 2003;44:254)
  - 104 women; mean f/u 11.9 months (8-20)
  - Objective cure = 90.4%
  - Subjective cure = 72%
  - De novo urge symptoms in 12%

TVT vs SPARC
4 studies at 2003 ICS

- Corcos et al – prospective, randomized comparing intra op and short term complications – **SIMILAR**
- Gauruder-Burmester et al – retrospective comparing outcomes at 12 weeks – **SAME** 87.3% cure for TVT: 85.9% for SPARC
- Dietz, et al – retrospective case-controlled study – **NO DIFFERENCE** in cure/improvement, satisfaction, SPARC less "poor stream"
- Gahandi, et al – retrospective comparing outcomes at 14 weeks 95.7% cure for TVT:76.2% for SPARC (p=.062)

Complications

- Minor complications
  - Transient voiding dysfunction
  - Hematoma formation
  - Bladder perforation (5%)
  - Vaginal extrusion of tape
- Major Complications
  - Tape erosion into urethra or bladder
  - Vascular injury &/or Neuropathy
  - Bowel injury
  - Urinary retention (2-3%)

Other Midurethral Polypropylene Slings

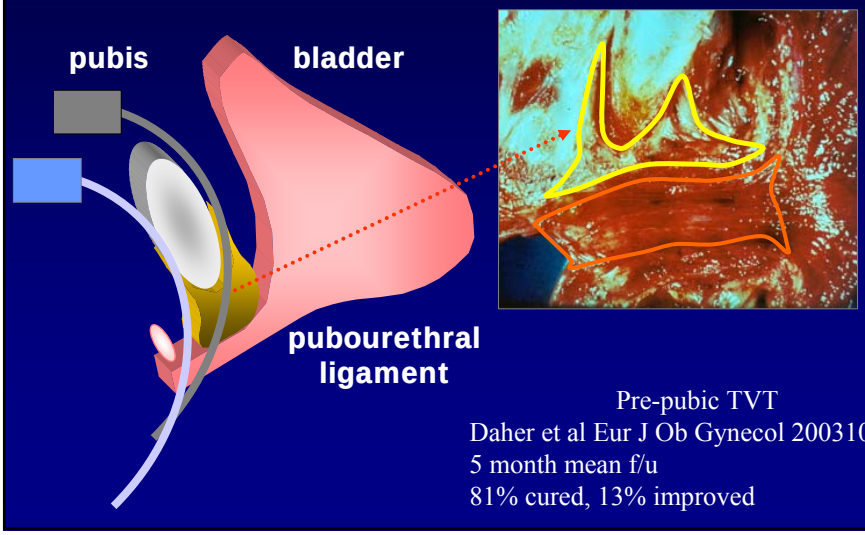
- Several commercial brands
- PVT (Cleveland Clinic)
  - "Homemade" 1.1 cm polypropylene sling placed with Stamey needles
- Raz distal urethral Prolene sling
  - Traditional dissection
  - Data at 2 years comparable to TVT

Midurethral Polypropylene Slings

- Decreased operative time (about 30 min)
- Choice of anesthesia
  - Local with sedation, regional, general
- Outpatient procedure
- Low morbidity
- 5 year outcomes (TVT) comparable to any other procedure for SUI

"Newer" Mid Urethral Slings

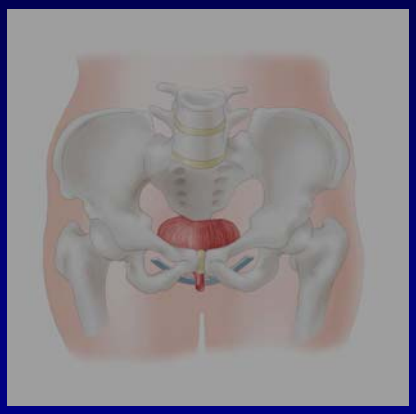
Subcutaneous Pre-pubic Sling



Pre-pubic TVT
Daher et al Eur J Ob Gynecol 2003107,205
5 month mean f/u
81% cured, 13% improved

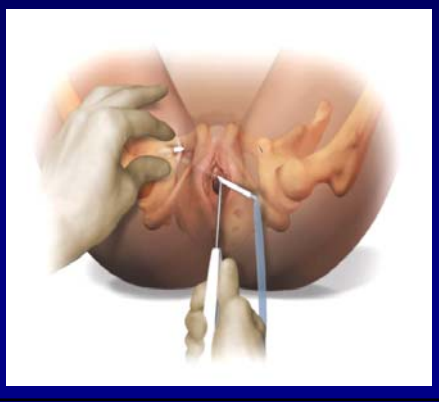
Trans Obturator Slings

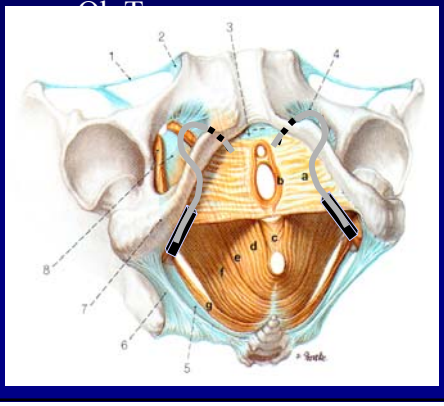
- Avoid retropubic space
- Theoretical decrease in potential complications
  - Bladder perforation reported
- Theoretical decrease in voiding dysfunction



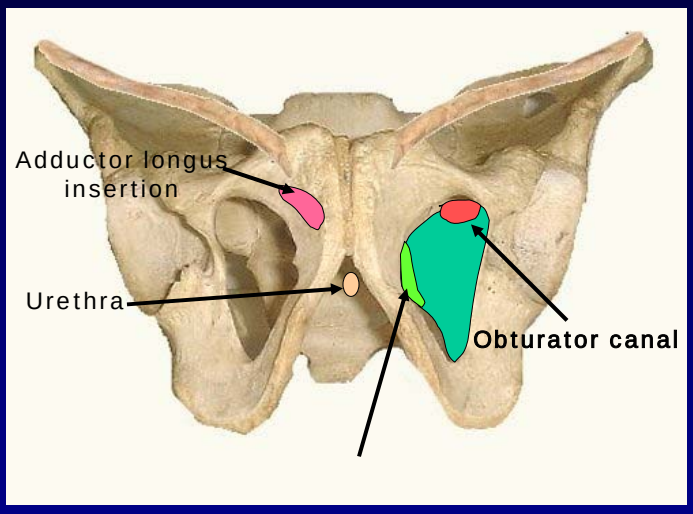
Trans Obturator Slings

- Inside - Out
  - TVT - Obturator
- Outside – In
  - Monarch

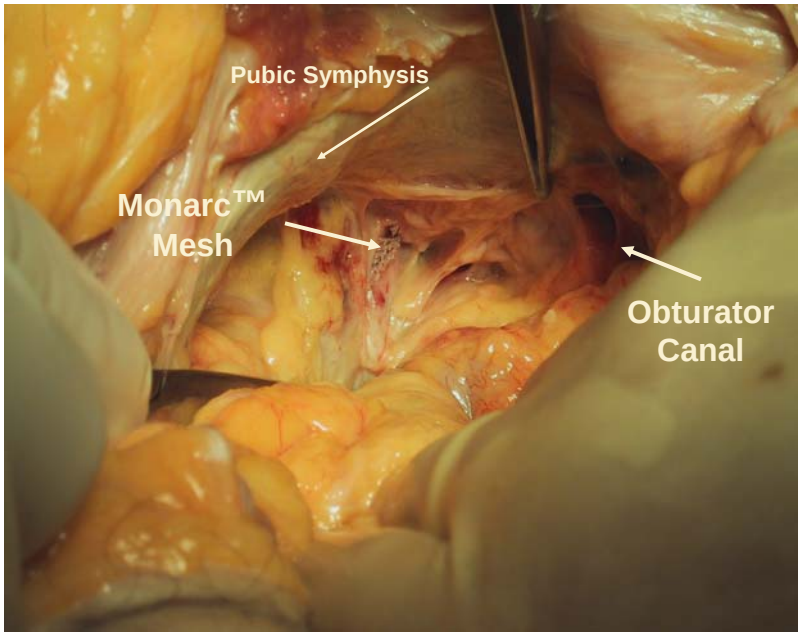




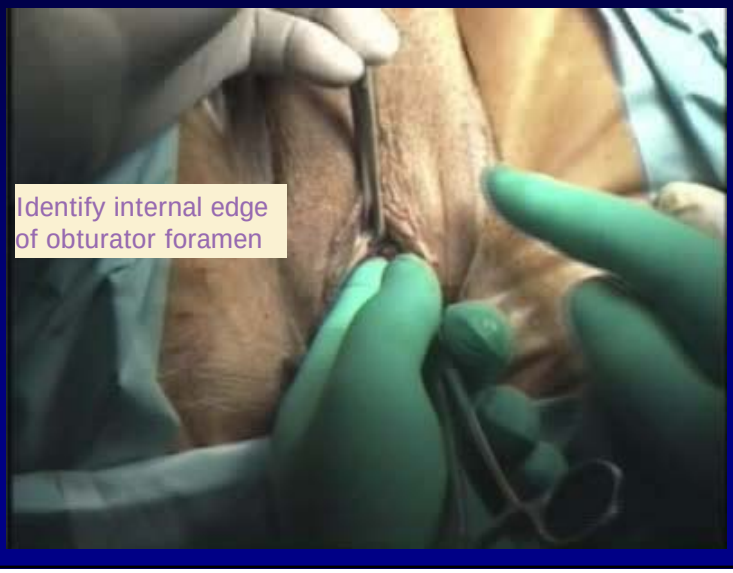
Obturator Anatomy



SAFE ENTRY ZONE FOR NEEDLE INSERTION

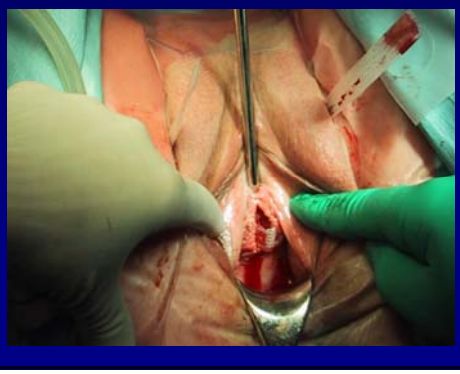


Outside-In Technique

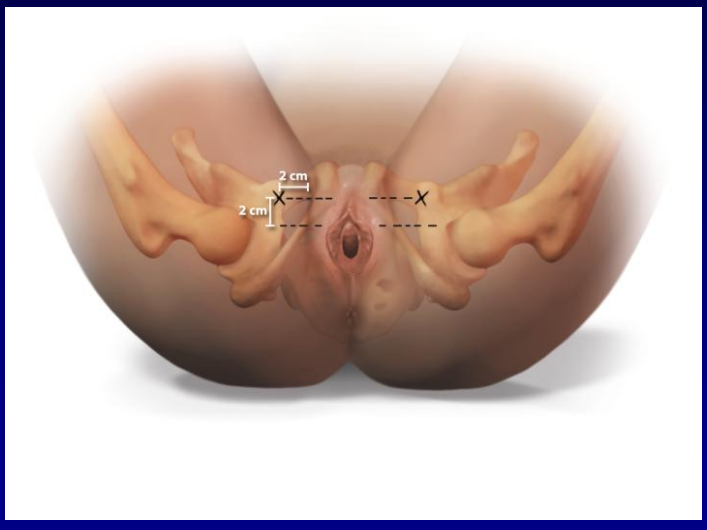


Outside – In Technique (Monarch)

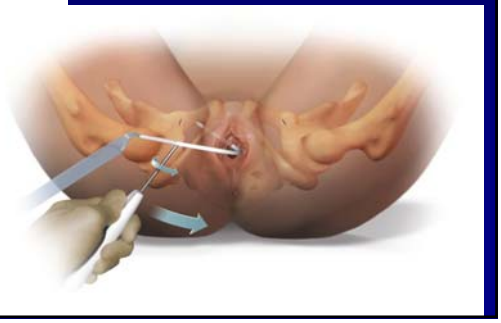
Needle Path and Placement



Inside – Out Technique (TVT-O)



Inside – Out Technique (TVT-O)



Inside – Out Technique (TVT-O)

Peer Reviewed Data as of 3/2004

- Outside – In
  - Delorme E at al Prog Urol 2003;13:656
  - Uratape (Obtape)
  - 32 patients, mean f/u = 17 months (13-29)
  - 90.6% cures, 9.4% improved
  - No intraop complications, 1 prolonged retention (4 weeks), 5 with obstructive voiding 2 de novo UUI
- Inside – Out
  - Leval Eur Urol 2003;44:724
  - 107 patients – feasibility study – SUI outcomes not reported
  - Mean operative time 14 minutes 97-20)
  - No bladder or urethral injuries

TVT vs TOT

deTayrac et al, Am J Ob Gyn 2004;190,602

- Randomized trial comparing TVT to TOT in 61 women
- Urodynamic SUI without DO
- Operative time shorter for TOT (14.8 vs 26.5 min)
- Urinary retention > 24 hrs. greater in TVT (25.8% vs 13.3%)
- At 1 year objective cure in 90% TOT vs 83% TVT
  - No difference

Trans Obturator Slings

- Early results encouraging
  - Minimal peer reviewed data
- No selection criteria
- At this time may consider for "select" cases
  - Prior retropubic surgery
  - Obesity

Factors Influencing Choice of Procedure

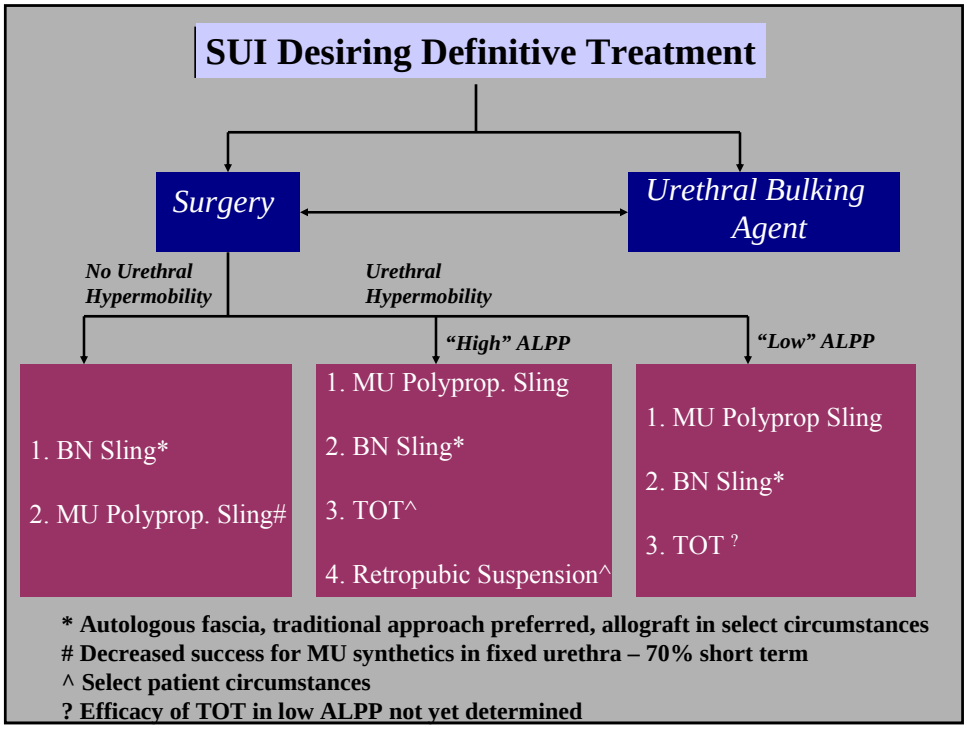
- SUI with urethral hypermobility
  - Midurethral synthetic slings provide excellent results with low morbidity
- SUI with no hypermobility
  - Type 3 SUI in the fixed urethra greater tension may be warranted – bladder neck sling preferred
- Occult SUI with prolapse repair
  - All types of slings applicable
- Complex cases
  - Failed prior surgery
  - Prior eroded synthetic
  - With urethral diverticulectomy or VVF repair

Role of Pubovaginal Sling In My Practice in 2004

- Fixed urethra (better efficacy over TVT)
  - Patient choice (70% short term success with TVT)
  - Prefer autologous
  - Older patients consider biological
- Prior problematic synthetic sling
- Significant radiation changes
- Simultaneous urethral reconstruction / urethral diverticulectomy
- Patient preference for autologous tissue

Stress Incontinence Surgery
Summary

- Alternative sling materials and techniques offer decreased OR time and patient convalescence
- Patients should be explained advantages and disadvantages of each, what is known and what is unknown
  - In the context of a particular patient's condition
- Long-term and chronic complications are similar for all operations
  - Voiding dysfunction, retention, de novo irritative Sx's


SUI Desiring Definitive Treatment
Surgery
Urethral Bulking Agent
No Urethral Hypermobility
Urethral Hypermobility
"High" ALPP
"Low" ALPP
1. BN Sling*
2. MU Polyprop. Sling#
1. MU Polyprop. Sling
2. BN Sling*
3. TOT^
4. Retropubic Suspension^
1. MU Polyprop Sling
2. BN Sling*
3. TOT ?
* Autologous fascia, traditional approach preferred, allograft in select circumstances
# Decreased success for MU synthetics in fixed urethra – 70% short term
^ Select patient circumstances
? Efficacy of TOT in low ALPP not yet determined