Surgery For Stress Incontinence: Choosing A Procedure In 2004

Victor W. Nitti, MD
Associate Professor and Vice Chairman
Department of Urology
NYU School of Medicine

How does the urethra stay 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

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

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

MMK

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

<table>
<thead>
<tr>
<th></th>
<th>1 yr.</th>
<th>3 yrs.</th>
<th>5 yrs.</th>
<th>&gt; 10 yrs.</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. pts</td>
<td>250</td>
<td>103</td>
<td>47</td>
<td>20</td>
</tr>
<tr>
<td>% cured SUI</td>
<td>94</td>
<td>94</td>
<td>95</td>
<td>95</td>
</tr>
<tr>
<td>% de novo UUI</td>
<td>3</td>
<td>5</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>% persistent UUI</td>
<td>23</td>
<td>26</td>
<td>31</td>
<td>41</td>
</tr>
</tbody>
</table>

- Overall 73% cured and 19% improved
Pubovaginal Sling
Morgan, et. al., J. Urol. 163: 1845, 2000

<table>
<thead>
<tr>
<th></th>
<th>2 yr.</th>
<th>3 yrs.</th>
<th>4 yrs.</th>
<th>5+ yrs.</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. pts</td>
<td>247</td>
<td>178</td>
<td>144</td>
<td>88</td>
</tr>
<tr>
<td>% cured SUI</td>
<td>93</td>
<td>91</td>
<td>88</td>
<td>85</td>
</tr>
<tr>
<td>% de novo UUI</td>
<td>7</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% persistent UUI</td>
<td>26</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- 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

• 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

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

* 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

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

* 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

- 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
Pelvikol vs. TVT
Arunkalaivanan and Barrington, Int Urogynecol J, 2003

- 142 women with SUI randomized to TVT or Pelvikol 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

  – 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 ≥ 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

<table>
<thead>
<tr>
<th>NAME</th>
<th>COMPOSITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mersilene</td>
<td>polyethylene terephthalate</td>
</tr>
<tr>
<td>Marlex</td>
<td>polypropylene</td>
</tr>
<tr>
<td>Prolene</td>
<td>polypropylene (Hernia mesh)</td>
</tr>
<tr>
<td>Prolene Soft</td>
<td>loosely woven (Gynemesh)</td>
</tr>
<tr>
<td>Teflon</td>
<td>polytetrafluoroethylene (PTFE)</td>
</tr>
<tr>
<td>Gore-tex</td>
<td>expanded PTFE</td>
</tr>
<tr>
<td>Silastic</td>
<td>silicone rubber + mersilene</td>
</tr>
</tbody>
</table>

### Loosely Woven Polypropylene Mesh Sling

- **inert material - large pore size**
- minimizes chance of colonization or infection
- facilitates vascular in-growth and tissue in-growth
Comparing: Graft Infection, Pore Size and Elasticity

<table>
<thead>
<tr>
<th></th>
<th>Infection</th>
<th>Pore Size (mm)</th>
<th>Elasticity N/mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>TVT</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SPARC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prolene</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marlex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mersilene</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>G-Tex S</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Teflon</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

- 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
  - Ob Tape

Obturator Anatomy

SAFE ENTRY ZONE FOR NEEDLE INSERTION

- Adductor longus insertion
- Urethra
- Obturator canal
Outside-In Technique

Identify internal edge of obturator foramen
Outside – In Technique (Monarch)

Needle Path and Placement

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

- No Urethral Hypermobility
  - 1. BN Sling*
  - 2. MU Polyprop. Sling#
- Urethral Hypermobility
  - "High" ALPP
    - 1. MU Polyprop. Sling
    - 2. BN Sling*
    - 3. TOT^ (Select patient circumstances)
    - 4. Retropubic Suspension^ (Select patient circumstances)
  - "Low" ALPP
    - 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