APPROACH TO STRESS URINARY INCONTINENCE : MIDURETHRAL SLINGS

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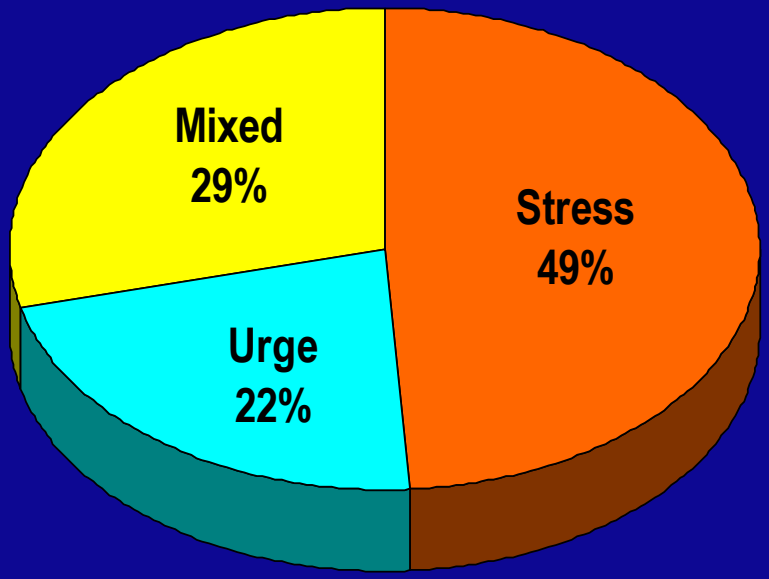
ICS SUI Definitions

- **Symptom**
  - Complaint of involuntary leakage on effort or exertion, or on sneezing or coughing
- **Sign**
  - Observation of involuntary leakage from the urethra, synchronous with exertion/effort, or sneezing or coughing
- **Diagnosis**
  - Urodynamic SUI: involuntary leakage of urine during CMG with increased abdominal pressure, in the absence of a detrusor contraction

SUI - Is the Most Common Type of UI in Women



Hampel C, et al. Urology. 1997;50 (suppl 6A):4-14.

STRESS URINARY INCONTINENCE (SUI)

- Failure of urethra to maintain water-tight seal during ”stress” conditions

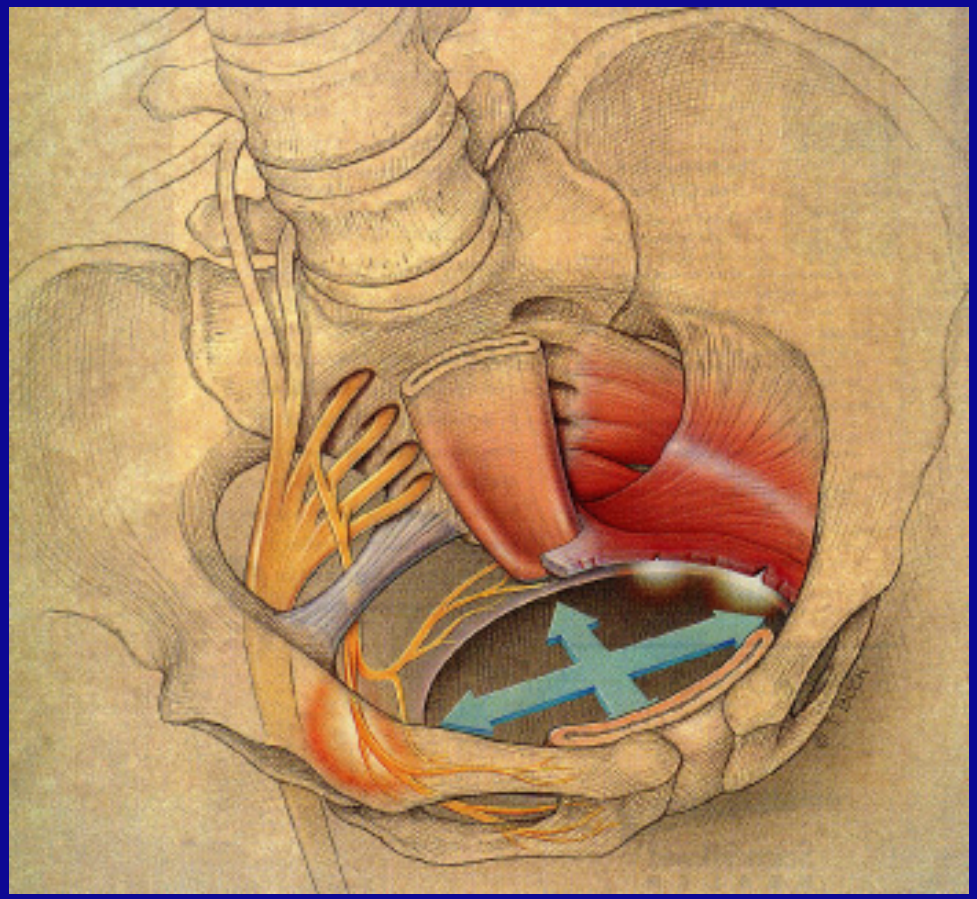
- Basic mechanisms of failure:
  - poor urethral support
  - intrinsic sphincter deficiency

ETIOLOGIC FACTORS FOR SUI:

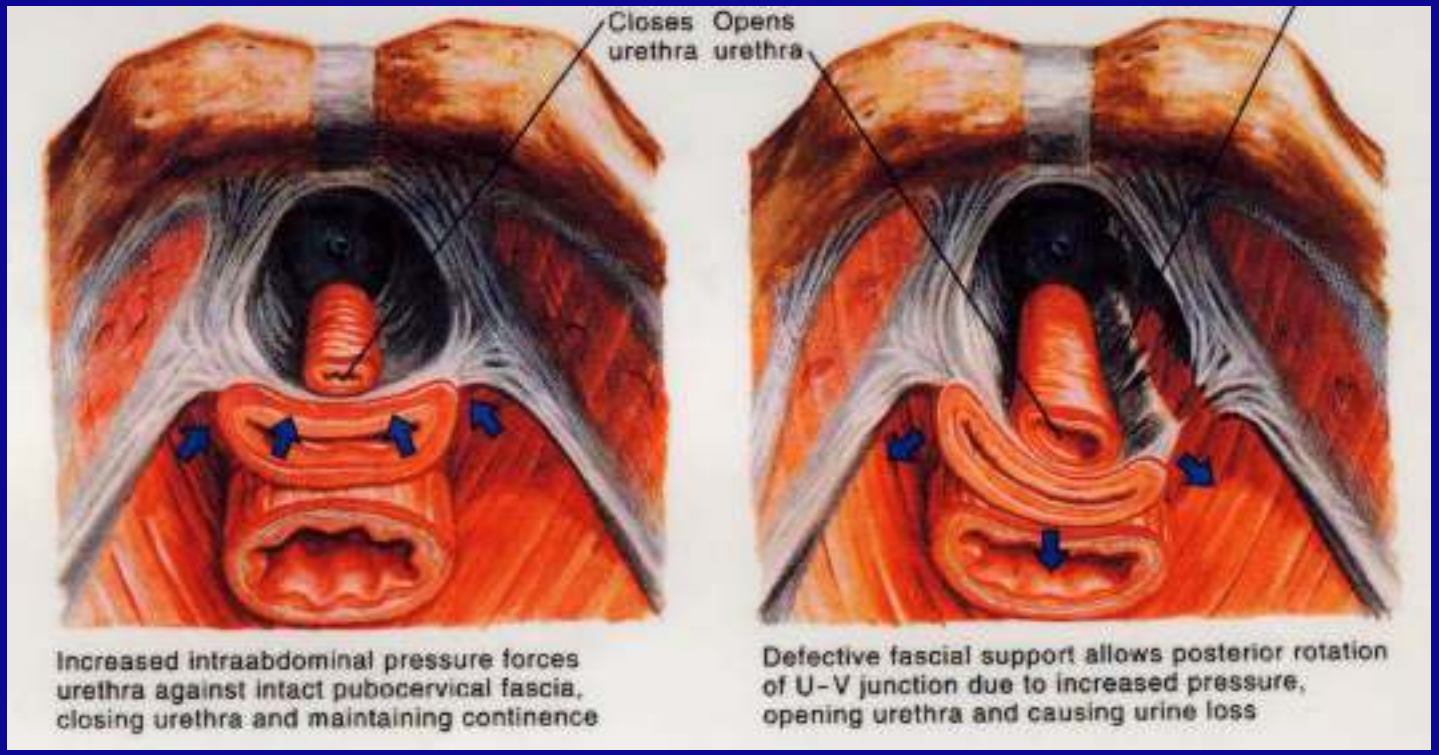
- Anatomic and neurological injury of the pelvic floor during childbirth
- Genetic susceptibility (tissue strength)
- Behavioral aspects (smoking, obesity, occupation)
- Confounding medical conditions (chronic pulmonary disease, aging, estrogen deficiency)

FUNCTIONAL PELVIC UNIT

- Connective tissue
- Pelvic muscles
- Nerves



Connective tissue disruption

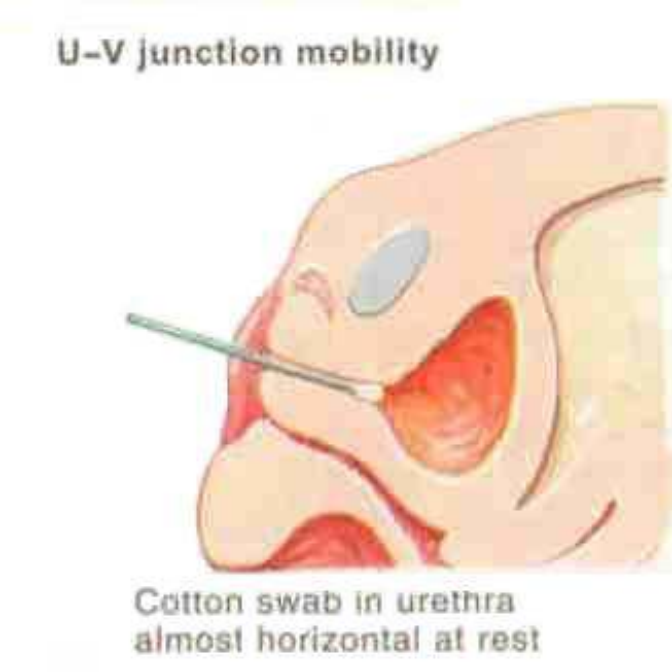


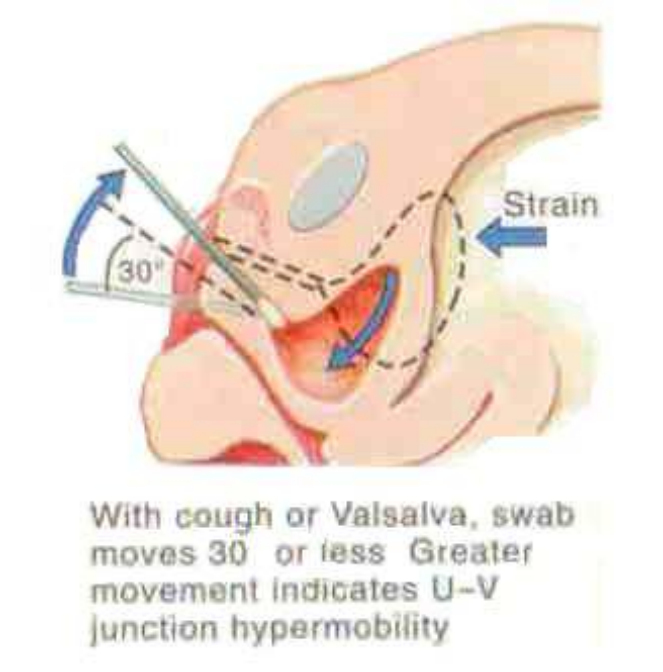
DeLancey J., Clinical Obstet and Gynecol, Vol 33, No.2, June 1990

Peschers U., DeLancey J., Urethral Support and Child birth: Obstet & Gynecol, Vol. 88, No 6, December 1996

URETHRAL HYPERMOBILITY

Exaggerated, upward angle of >12 degrees at rest and >30 during Valsalva is considered evidence of urethral hypermobility



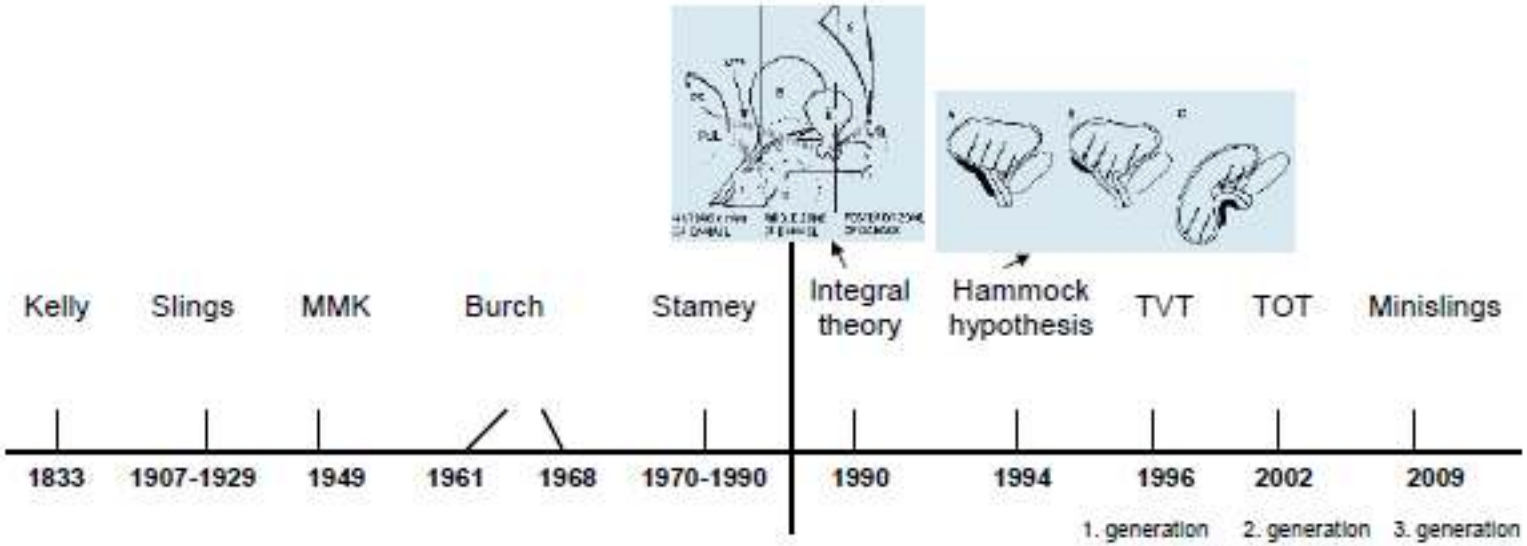


SPHINCTERIC INSUFFICIENCY AND HYPERMOBILITY

Staskin DR. Classification of voiding dysfunction. In: Cardozo L, Staskin DR, eds. Textbook of Female Urology and Urogynaecology. London: Isis Medical Media;2001:84-89.

EVOLUTION IN THE AIMS OF SUI SURGERY

Compress outlet	(Kelly plication)
Reposition and restore sphincter unit	(Anterior colporrhaphy)
Restore pressure transmission differential	(MMK, Burch, Stamey)
Coapt outlet at rest - ISD	(Sling, Bulking agents)
Provide backboard	(Tensionfree MUSling)



Empirically based

Pathophysiological theory defined

HISTORICAL ANTI-INCONTINENCE SURGERIES

ANTERIOR COLPORRHAPHY/PLICATION

- *ICI (2002)*[1]
  - "…Not normally recommended… for the cure of stress incontinence"

- *COCHRANE COALITION*[2]
  - "…Should be restricted to women deemed unsuitable for alternative treatment"
- Useful only for central defect cystocele

1. *Abrams P et al. Incontinence. 2nd International Consultation on Incontinence, Paris, July 1-3, 2001. 2nd Edition, 2002.*
2. *Cochrane Library, Volume 1, 2003.*

HISTORICAL ANTI-INCONTINENCE SURGERIES

MARSHALL-MARCHETTI-KRANTZ (MMK) (1949)

- AUA (1997)[1] - mean % cure/dry
  - 1-2 yr.: 72 (55-85)
  - 2-4 yr.: 83 (75-89)
  - > 4 yr.: 83 (76-88)

- ICI-2[2]
  - cure: 88%
  - improvement: 91%
  - complications: overall, 22%; osteitis, 2.5%; mortality, 0.2%

1. AUA Incontinence Clinical Guidelines Panel, J Urol. Sept. 1997.
2. Abrams P et al. Incontinence. Report of the 2nd International Consultation on Incontinence, Paris, July 1-3, 2001. 2nd Edition, 2002.

HISTORICAL ANTI-INCONTINENCE SURGERIES

BURCH PROCEDURE (John Burch -1961)

- AUA (1997)[1] - mean % cure/dry
  - 1-2 yr: 85 (78-91)
  - 2-4 yr: 84 (79-88)
  - 4 yr: 83 (75-90)

- ICI-2[2] - follow-up, 9 mo -16 yr
  - Cure/Dry: 79%
  - Improvement: 90%
  - With time, decrease in continence

1. *AUA Incontinence Clinical Guidelines Panel, J Urol. Sept. 1997.*
2. *Abrams P et al. Incontinence. Report of the 2nd International Consultation on Incontinence, Paris, July 1-3, 2001. 2nd Edition, 2002.*

HISTORICAL ANTI-INCONTINENCE SURGERIES

BURCH PROCEDURE: COMPLICATIONS

ICI-2:

- Voiding dysfunction: 2%-27% (mean, 10.3%)
- De novo DI: 8%-27% (mean, 17%)
- Prolapse: 3%-27% (mean, 13.6%) at 5 yr
- Mortality: 0%

Abrams P et al. Incontinence. Report of the 2nd International Consultation on Incontinence, Paris, July 1-3, 2001. 2nd Edition, 2002.

HISTORICAL ANTI-INCONTINENCE SURGERIES

LAPAROSCOPIC BURCH PROCEDURE

ICI-2[1]:

- "The results … are conflicting … until longer studies are available no conclusions can be drawn … evidence suggests that the results are surgeon-dependent"

McDougall EM[2]

- The laparoscopic bladder neck suspension in 3 and 4 years follow-up has achieved a success rate of only 30%, with a mean time to failure of 18 months.

1. *Abrams P et al. Incontinence. Report of the 2nd International Consultation on Incontinence, Paris, July 1-3, 2001. 2nd Edition, 2002*
2. *McDougall EM . Laparoscopic management of female urinary incontinence; Urol Clin North Am. 2001 Feb;28(1):145-9, x.*

HISTORICAL ANTI-INCONTINENCE SURGERIES

NEEDLE SUSPENSION PROCEDURES (NSP)

- *Pereyra (1959)– rationale:*
  - Avoid tearing out of sutures (MMK)
  - Avoid opening retropubic space

- *Stamey (1973)*
  - Cystoscopic control for suture placement/bladder neck closure
  - Bolsters support bladder neck

- *Raz (1981)*
  - Helical sutures for endopelvic fascia, periurethral tissues
  - Emphasis on the “good stuff”

HISTORICAL ANTI-INCONTINENCE SURGERIES

NEEDLE SUSPENSION PROCEDURES (NSP)

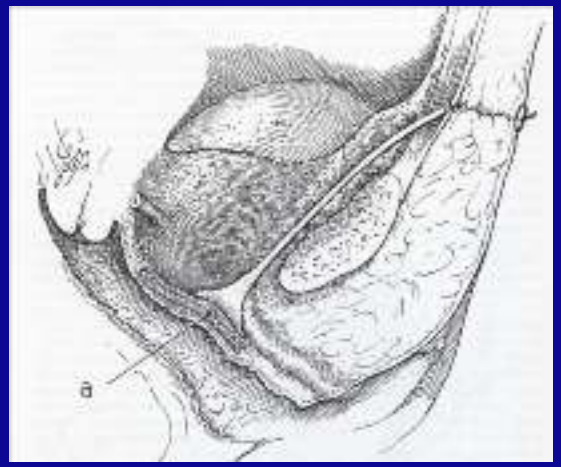
- "… initial success rates … are not maintained with time … risk of failure is higher than with RPS … few, if any, indications to perform needle suspension procedure"[1]
- AUA – cure/dry rates of NSP – at 4 years only 67%[2]
- "For surgeons who are experienced in sling operations and can perform them with minimal morbidity, NS offers no significant advantages"[3]

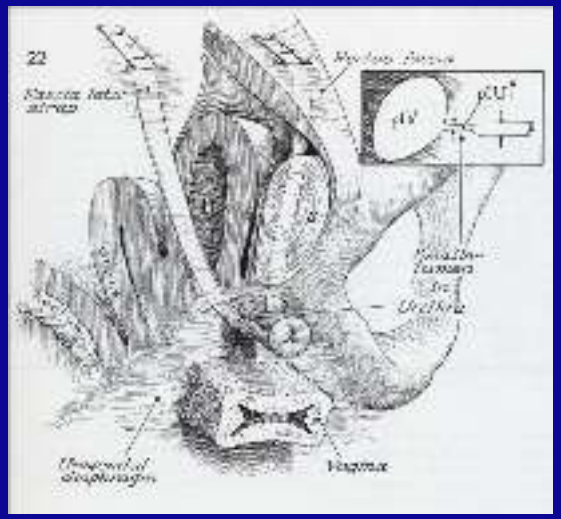
1. *Abrams P et al. Incontinence. Report of the 2nd International Consultation on Incontinence, Paris, July 1-3, 2001. 2nd Edition, 2002.*
2. *Leach G et al. Female Stress Urinary Incontinence Clinical Guidelines Panel summary report on surgical management of female stress urinary incontinence; J Urol 1997; 158: 875-80*
3. *Erickson DR. J Urol. 2001;165:1612-1613.*

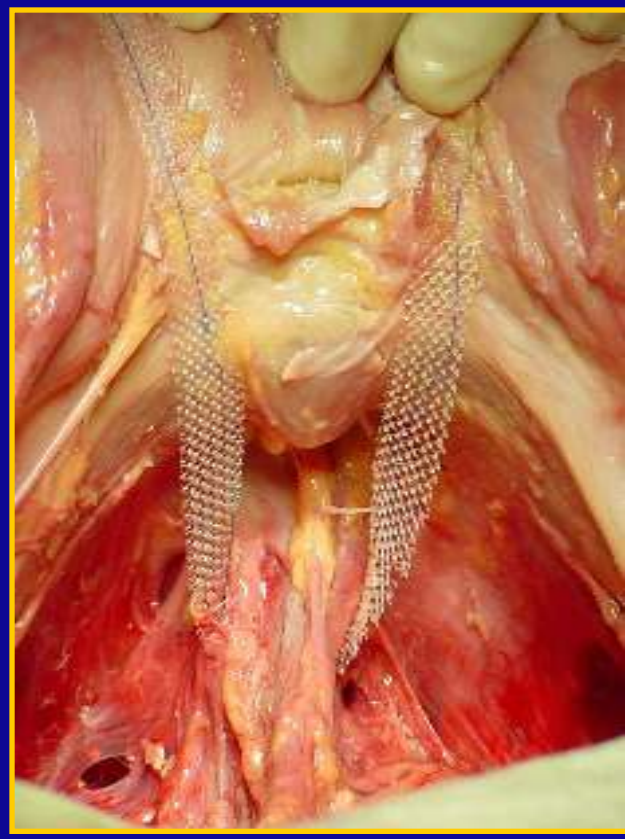
HISTORICAL ANTI-INCONTINENCE SURGERIES

PUBOVAGINAL SLING: "CLASSIC"

- Originally, compress and partially obstruct urethra
  - high incidence of voiding dysfunction
- Provide backboard and support during effort
  - for gross ISD, need to appose walls at rest







MIDURETHRAL SLING ERA

PUBOVAGINAL SLING: NEW CONCEPTS

- Thinking has changed
  - obstruction unnecessary[1]
  - no need to increase resting Pura unless gross ISD (McGuire)
  - useful for support and ISD
- Classic location is bladder neck/proximal urethra
  - Raz: midurethra[2]

1. *McGuire EJ and Lytton B. J Urol. 1978;119:82-84.*
2. Rodriguez LV. Curr Urol Rep. 2001;2:399-406.

MIDURETHRAL SLING ERA

PUBOVAGINAL SLING:

- *NATURAL*
  - Rectus fascia: full-length, patch
  - Fascia lata: autologous, allogenic
  - Dermis: porcine, human
  - Dura
  - Other

MATERIALS

- *SYNTHETIC*
  - Gore-Tex
  - Nylon
  - Perlon
  - Mersilene
  - Silastic
  - Polyglactin mesh
  - Prolene

MIDURETHRAL SLING ERA

PUBOVAGINAL SLING: SUCCESS RATES

- Ranges of success more consistent than with other procedures
- *AUA*[1]
  - RPS and slings are most effective procedures for long-term success, but they are associated with higher complication rates and longer convalescence
- *ICI-2*[2]
  - Effective for SUI
  - Cure rate 80%; improvement rate 90%
  - Autologous material suggested to have higher cure and lower complication rates, but long-term studies needed to see whether material influences outcome
  - 10-year continence rate approximates 1-year rate

1. *Leach G et al. Female Stress Urinary Incontinence Clinical Guidelines Panel summary report on surgical management of female stress urinary incontinence; J Urol 1997; 158: 875-80*
2. *Abrams P et al. Incontinence. Report of the 2nd International Consultation on Incontinence, Paris, July 1-3, 2001. 2nd Edition, 2002*

MIDURETHRAL SLING ERA

PUBOVAGINAL SLING:

- Autologous grafts
  - Voiding dysfunction: 2%-20%
  - Long-term Self-Cath: 1.5%-7.8%
  - De novo DI: 3%-23%
- Allogenic cadaver grafts
  - No higher erosion rates
  - Higher long-term material failure (> 20%)

COMPLICATIONS

- Synthetics
  - Increased risk of erosion and sinus formation?
    - Vaginal erosion: 0%-16%
    - Urethral erosion: 0%-5%
    - De novo DI: 4%-66%
    - Removal or revision: 1.8%-35%

Data compiled by ICI (2002), AUA (1997), Chaikin and Blaivas (2001), Jensen and Rufford (2001), Rodriguez et al (2001).

Midurethral Slings

1. generation	2. generation	3. generation
TVT 1996	TOT 2001	Minislings 2008
Retropubical	Transobturator	Transvaginal
Advantages / Disadvantages		
Bladder, bowel, vascular injury, ISD suitable	↓ incidence of retention, faster reconvalescence, groin pain	↓ Less tissue trauma, less pain

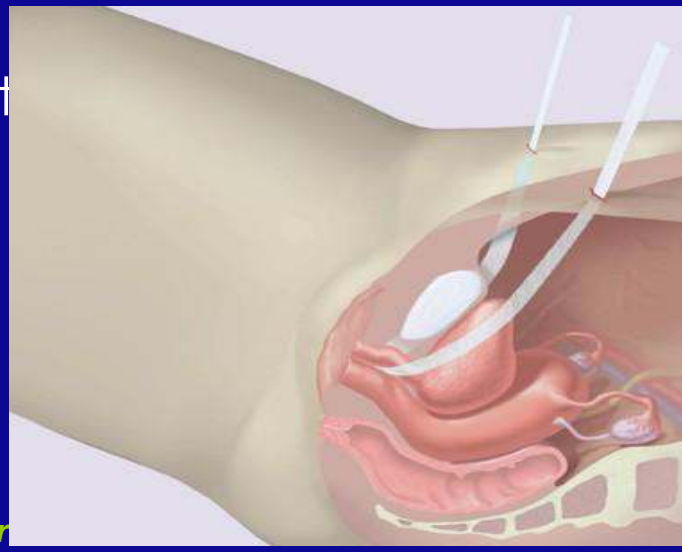
MIDURETHRAL SLING ERA

TENSION-FREE VAGINAL TAPE (TVT)

- Introduced 1995-1996 by Ulmsten and Petros
- Knotted, monofilament, Prolene mesh,

>75 micron pore size, under midurethra

- Based on a "integral theory" (Ulmsten/Petros)
- Tape lies free at rest, not fixed
- Does not correct hypermobility
- Tape fixed by tissue incorporation/in growt



TENSION-FREE VAGINAL TAPE (TVT)

- Success rate ≈ open colposuspension
- Cure of SUI: 65%-91%
- Improvement: 94%-97%
- Follow-up: 2-5 years

Data from Ulmsten et al (1990), (1998), (2000); Kuuva and Nilsson (2000); ICI (2002); Ward and Hilton (2002).

Midurethral Slings

Name	Type	Manufacturer
TVT	Retropubic 'bottom-top'	Ethicon
Advantage	Retropubic 'bottom-top'	Boston Scientific
SPARC	Retropubic 'top-bottom'	AMS
Lynx	Retropubic 'top-bottom'	Boston Scientific
Prefyx PPS	Pre-pubic 'bottom-top'	Boston Scientific
Monarc	Transobturator 'outside-in'	AMS
ObTryx	Transobturator 'outside-in'	Boston Scientific
Aris	Transobturator 'outside-in'	Coloplast
TVT-O	Transobturator 'inside-out'	Ethicon
MiniArc	Single Incision	AMS
TVT-Secur	Single Incision	Ethicon

TABLE 1
Some commonly used commercially available type I mesh slings slings (adopted from Rapp and Kobashi, 2008 [14])

TVT → Ulmsten and Petros 1995

SPARC → Deval et al 2003

TOT → De Lorme et al 2003

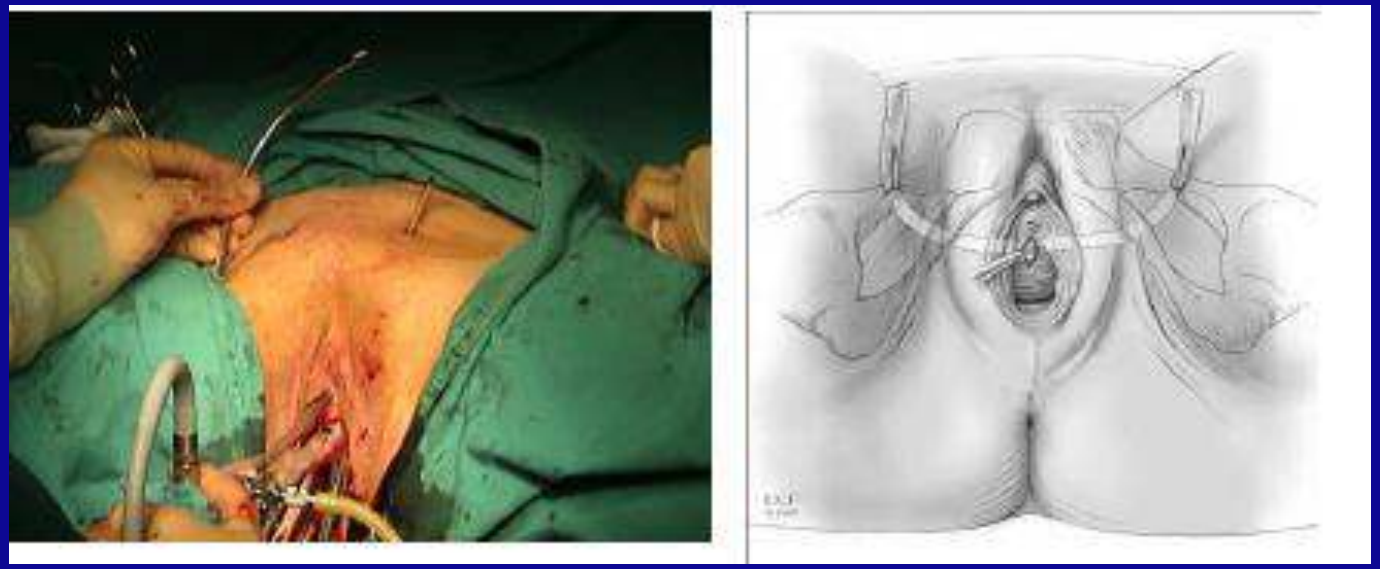
TVT-O → de Laval 2003

TVT, TOT and Minislings

- New gold standard in the treatment of SUI is low-tension midurethral slings
- Easy and fast for both the patient and the surgeon
- Type 1 mesh (macroporous-monofilament) reduces erosion and infection rates

MIDURETHRAL SLING MECHANISM

- Major role is to provide dynamic urethral kinking at increased IAP
- Neo pubourethral ligament reconstruction
- Endopelvic fascial reconstruction
- No tension during rest
- Correction of hypermobility ???
- Reinforcement of internal sphincter???

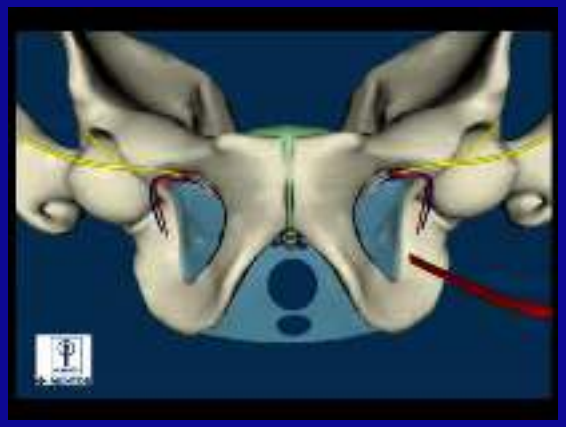


Neo pubourethral ligament reconstruction
Endopelvic fascial reconstruction

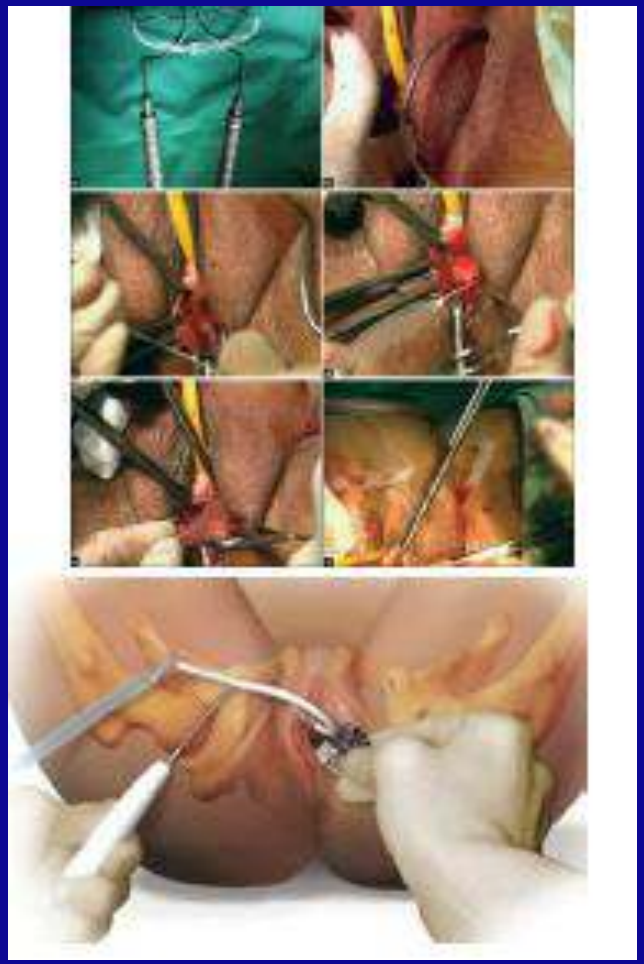
Trans-Obturator Tape (TOT)

- 2001 by Delorme E and deTayrac R
- Anchoring through the obturator foramen
- Short-term cure rates: 80-90%
- At 3 month postop patients with UCP<42 cm H2O – 5 times more likely to fail TO vs. RP procedure
- Shorther OR time
- Complications:

  Less bladder perf but, vaginal perf, urethral injury, postop thigh pain, severe hematoma



TOT & TVT-O



- Monarc TOT (TOT. AMS)
- TVT Obturator (TVT-O, Gynecare)

- Basically the same

RP-TVT vs. TO-TVT:

12 RCTS: RP-TVT vs. Inside-out &
9 RCTs: RP-TVT vs. Outside-in &
1 RCT: comparing all three

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European Association of Urology

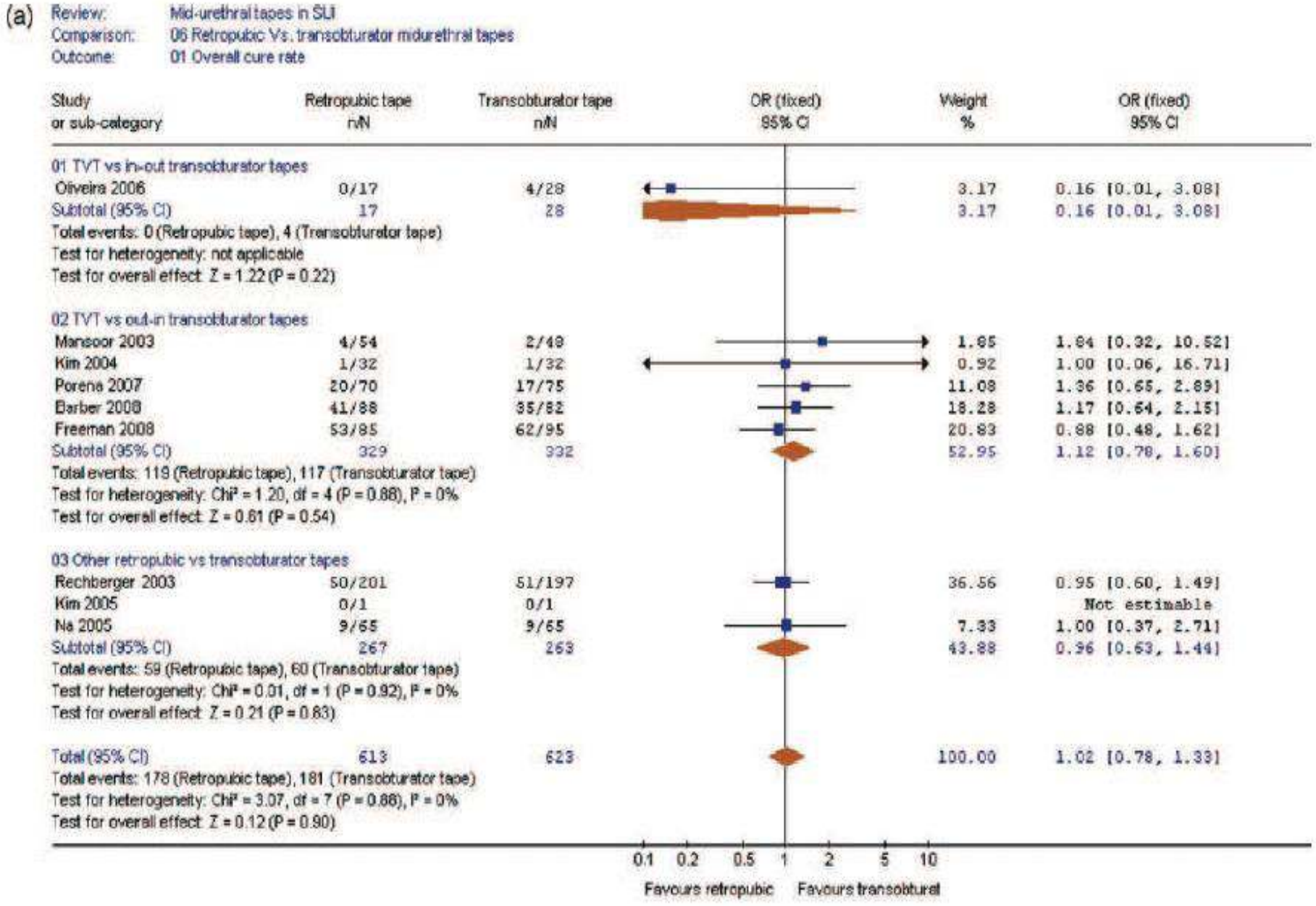
Platinum Priority – Female Urology – Incontinence

Editorial by Firouz Daneshgari on pp. 239–241 of this issue

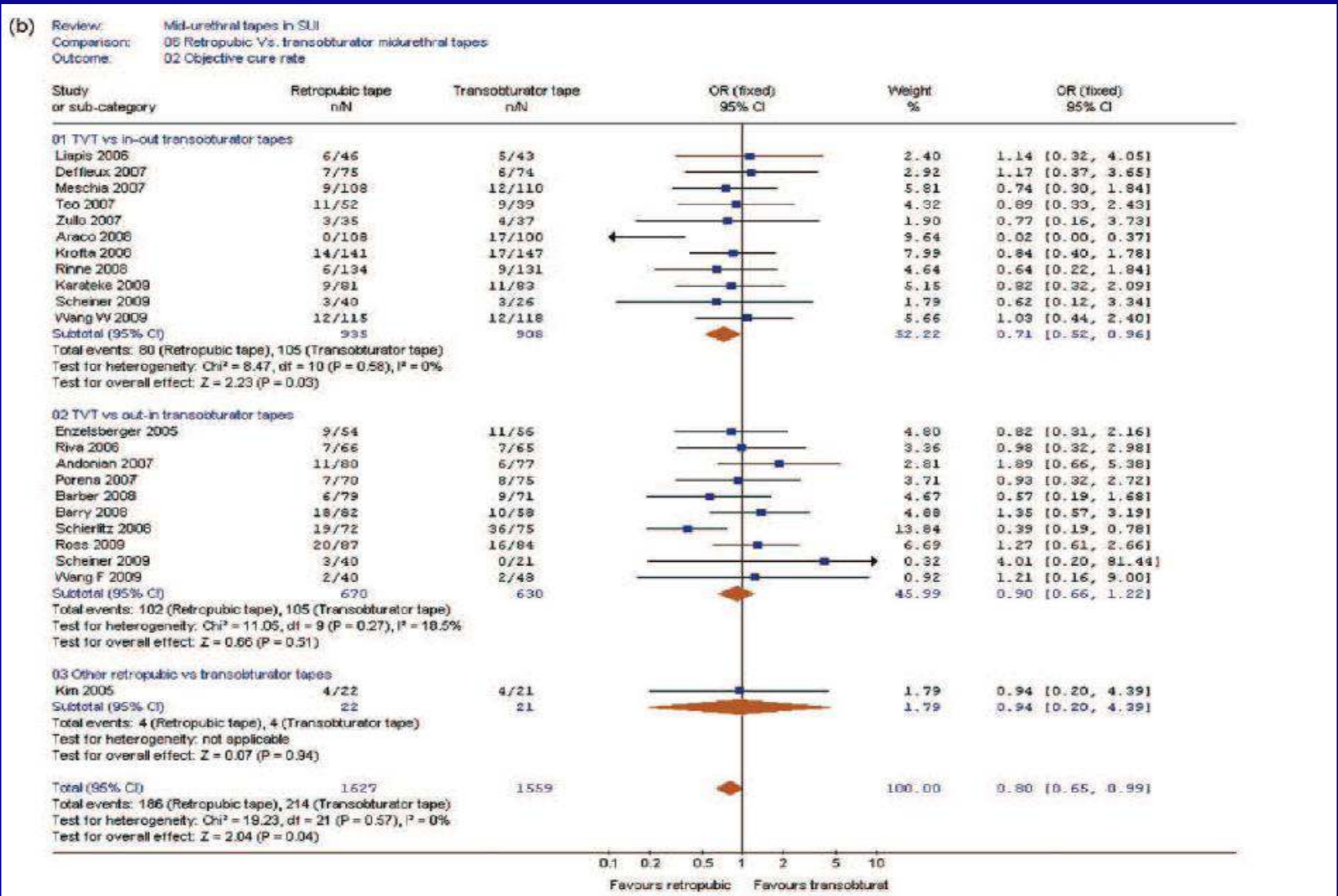
Updated Systematic Review and Meta-Analysis of the Comparative Data on Colposuspensions, Pubovaginal Slings, and Midurethral Tapes in the Surgical Treatment of Female Stress Urinary Incontinence

Giacomo Novara [a,], Walter Artibani [b], Matthew D. Barber [c], Christopher R. Chapple [d], Elisabetta Costantini [e], Vincenzo Ficarra [a], Paul Hilton [f], Carl G. Nilsson [g], David Waltregny [h]*

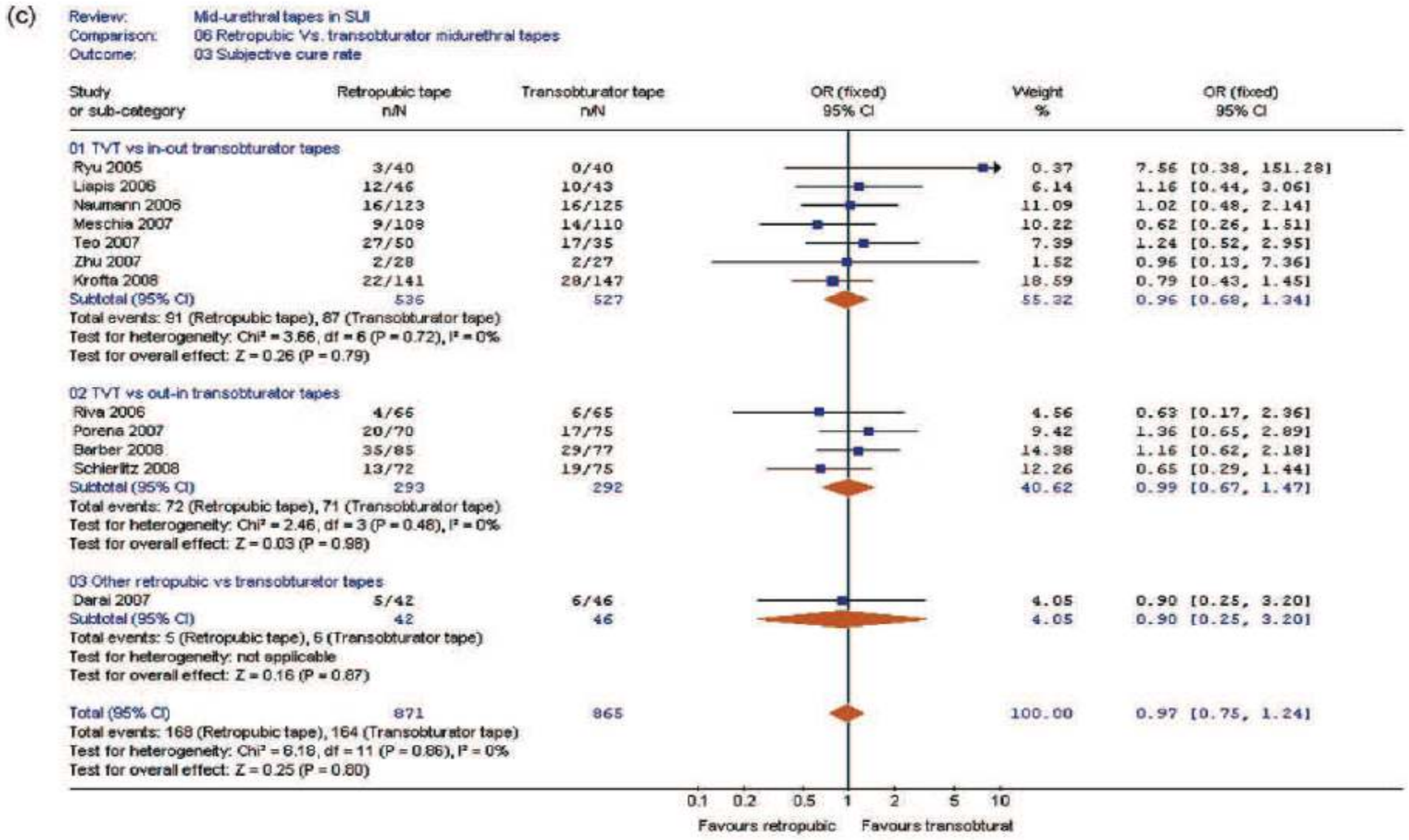
RP TVT vs TO TVT Overall Cure Rates



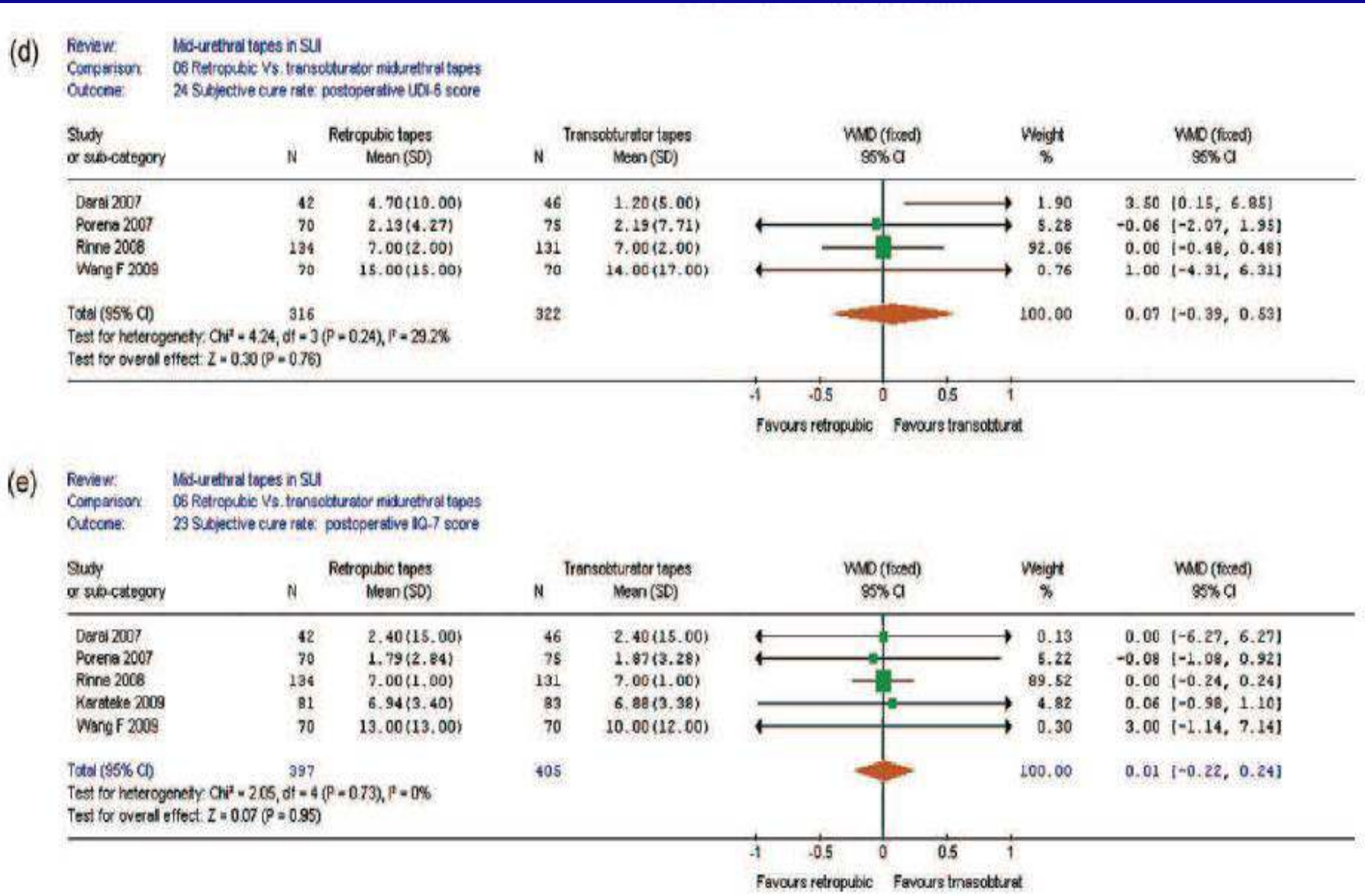
Outcome


(b)
Review: Mid-urethral tapes in SUI
Comparison: 05 Retropubic V's. transobturator midurethral tapes
Outcome: 02 Objective cure rate
Study or sub-category
Retropubic tape n/N
Transobturator tape n/N
OR (fixed) 95% CI
Weight %
OR (fixed) 95% CI
01 TVT vs in-out transobturator tapes
Liapis 2006 6/46 5/43 2.40 1.14 [0.32, 4.05]
Deffieux 2007 7/75 6/74 2.92 1.17 [0.37, 3.65]
Meschia 2007 9/108 12/110 5.81 0.74 [0.30, 1.84]
Teo 2007 11/52 9/39 4.32 0.89 [0.33, 2.43]
Zullo 2007 3/35 4/37 1.90 0.77 [0.16, 3.73]
Araco 2008 0/108 17/100 9.64 0.02 [0.00, 0.37]
Krofta 2008 14/141 17/147 7.99 0.84 [0.40, 1.78]
Rinne 2008 6/134 9/131 4.64 0.64 [0.22, 1.84]
Karateke 2009 9/81 11/83 5.15 0.82 [0.32, 2.09]
Scheiner 2009 3/40 3/26 1.79 0.62 [0.12, 3.34]
Wang W 2009 12/115 12/118 5.66 1.03 [0.44, 2.40]
Subtotal (95% CI) 935 908 52.22 0.71 [0.52, 0.96]
Total events: 80 (Retropubic tape), 105 (Transobturator tape)
Test for heterogeneity: Chi² = 8.47, df = 10 (P = 0.58), I² = 0%
Test for overall effect: Z = 2.23 (P = 0.03)
02 TVT vs out-in transobturator tapes
Enzelsberger 2005 9/54 11/56 4.80 0.82 [0.31, 2.16]
Riva 2006 7/66 7/65 3.36 0.98 [0.32, 2.98]
Andonian 2007 11/80 6/77 2.81 1.89 [0.66, 5.38]
Porena 2007 7/70 8/75 3.71 0.93 [0.32, 2.72]
Barber 2008 6/79 9/71 4.67 0.57 [0.19, 1.68]
Barry 2008 18/82 10/58 4.68 1.35 [0.57, 3.19]
Schierlitz 2008 19/72 36/75 13.84 0.39 [0.19, 0.78]
Ross 2009 20/87 16/84 6.69 1.27 [0.61, 2.66]
Scheiner 2009 3/40 0/21 0.32 4.01 [0.20, 81.44]
Wang F 2009 2/40 2/48 0.92 1.21 [0.16, 9.00]
Subtotal (95% CI) 670 630 45.99 0.90 [0.66, 1.22]
Total events: 102 (Retropubic tape), 105 (Transobturator tape)
Test for heterogeneity: Chi² = 11.05, df = 9 (P = 0.27), I² = 18.5%
Test for overall effect: Z = 0.66 (P = 0.51)
03 Other retropubic vs transobturator tapes
Kim 2005 4/22 4/21 1.79 0.94 [0.20, 4.39]
Subtotal (95% CI) 22 21 1.79 0.94 [0.20, 4.39]
Total events: 4 (Retropubic tape), 4 (Transobturator tape)
Test for heterogeneity: not applicable
Test for overall effect: Z = 0.07 (P = 0.94)
Total (95% CI) 1627 1559 100.00 0.80 [0.65, 0.99]
Total events: 186 (Retropubic tape), 214 (Transobturator tape)
Test for heterogeneity: Chi² = 19.23, df = 21 (P = 0.57), I² = 0%
Test for overall effect: Z = 2.04 (P = 0.04)
0.1 0.2 0.5 1 2 5 10
Favours retropubic
Favours transobturat

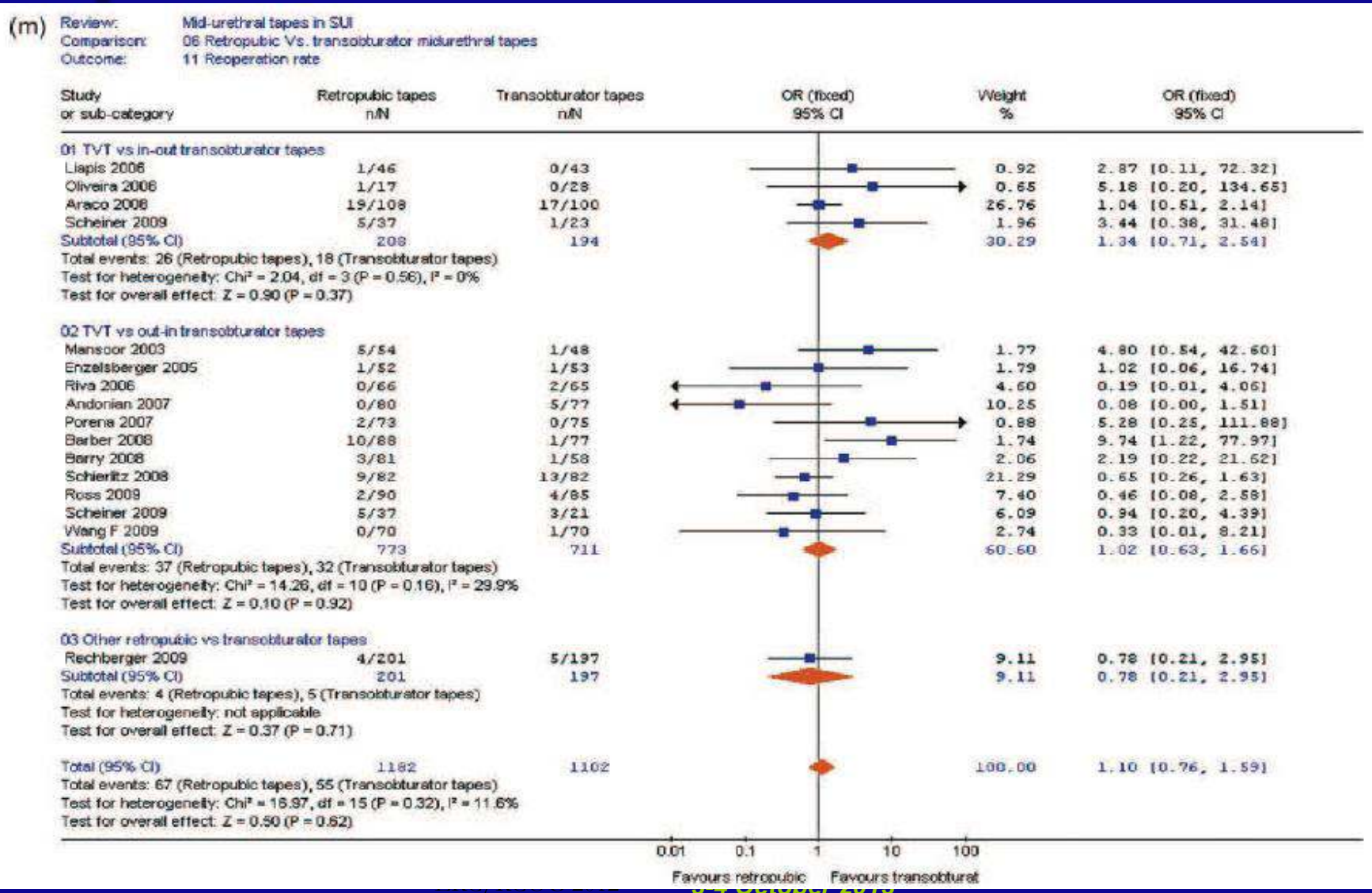
RP-TVT vs. TO-TVT: Patient - Reported Outcome



RP-IVT vs. TO-IVT: Quality of Life



RP-TVT vs. TO-TVT: Re-operation rates



RP-TVT vs. TO-TVT: Complications

^ RP-TVT

- LUT injury or vaginal perforations **(OR: 2.5; 95% CI OR: 1.75–3.57; p < 0.0001)**
- Postoperative hematoma **(OR: 2.62; 95% CI OR: 1.35–5.08; p = 0.005)**
- Storage LUTS e.g. Urgency **(OR: 1.35; 95% CI OR: 1.05–1.72; p = 0.02)**

^ TO-TVT

- Vaginal erosion were slightly higher following TOT **(OR: 0.64; 95% CI OR: 0.41–0.97; p = 0.04;** Obtape©)
- Groin/ Thigh Pain –Latthe BJOG 2007/ Teo R J Urol 2010

Long- Term FU

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Platinum Priority – Female Urology – Incontinence

Editorial by Elisaberta Costantini and Massimo Lazzeri on pp. 678–679 of this issue

Tension-Free Vaginal Tape Versus Transobturator Suburethral Tape: Five-Year Follow-up Results of a Prospective, Randomised Trial

Roberto Angioli[a], Francesco Plotti[a], Ludovico Muzii[a], Roberto Montera[a,], Pierluigi Benedetti Panici[b], Marzio Angelo Zullo[a]*

RCT: TO-TVT vs. RP –TVT 5 Years Follow-up:

- Patient reported success rate: 62% vs. 60% &
- Objective success 72.9% vs. 71.4%

Minimally Invasive / Mini / Single İncision Slings

- Midurethral positioned polyprolene mesh
- Minimal dissection to conserve periurethral nerves and microvasculature
- No suture fixation
- Not to elevate just to provide resistant backbone to urethra

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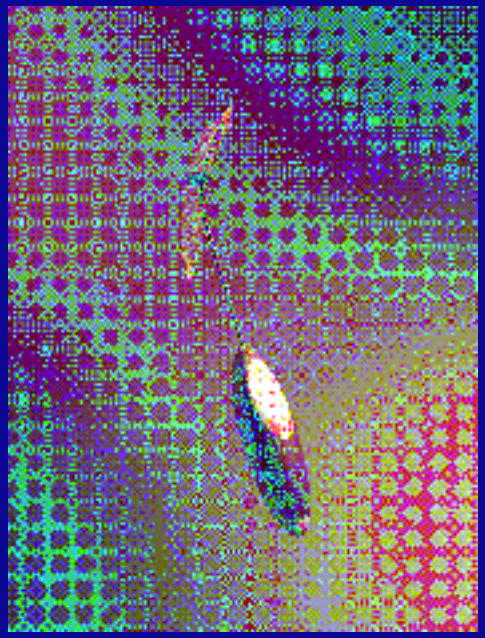
"NEEDLELESS" SLINGS

TVT – Secure

Ethicon

Mini-Arc



AMS

Needleless

Neomedic

TVT-SECUR

- Neither the retropubic space nor the transobturator route is passed and short-term results are similar with conventional TOT
- Results are lacking for TVT-S for longer than 1 year

Female Urology

Better Short-term Outcomes With the U-Method Compared With the Hammock Technique for the Implantation of the TVT-SECUR Under Local Anesthesia

Louis-Olivier Gagnon and Le Mai Tu

Urology 2010;75:1060–4

Table 3. Success rate

	Hammock	U-Method	Total	*P* Value
Improvement in continence symptoms—number				
1 week	16/22 (82%)	18/24 (75%)	34/46 (78%)	.7254
2 months	18/21 (86%)	23/24 (96%)	41/45 (91%)	.2481
6 months	11/16 (69%)	22/22 (100%)	33/38 (87%)	.0087*
Satisfaction rate—number				
1 week	15/22 (68%)	18/24 (75%)	33/46 (72%)	.7462
2 months	17/21 (81%)	21/24 (88%)	38/45 (84%)	.4213
6 months	11/16 (69%)	21/22 (95%)	32/38 (84%)	.0647

* Statistically significant difference.

Table 4. Complications

	Hammock	U-Method	Total	*P* Value
Perioperative—number				
Urethral laceration	0	1 (4%)	1 (2%)	1.0000
Bladder laceration	0	0	0	1.0000
Postoperative—number				
Partial tape exposure	8 (36%)	0	8 (17%)	.0028*
Transient urinary retention	0	2 (8%)	2 (4%)	.1902

MINIARC

- Self fixating tips into obturator muscles
- Less common mesh related complications, de novo urgency and sexual dysfunction

Needleless SLING

- Surface area of the mesh
- The largest the Best ???

SIMS vs. SMUS:

9 RCTs / 758 Women In TVT-S (n=6), Mini-Arc (n=2) and Ophira (n=1)

6-12 Months Follow-up.

EURURO-3910; No. of Pages 13

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EUROPEAN UROLOGY XXX (2011) XXX–XXX

available at www.sciencedirect.com
journal homepage: www.europeanurology.com

European Association of Urology

Review – Female Urology – Incontinence

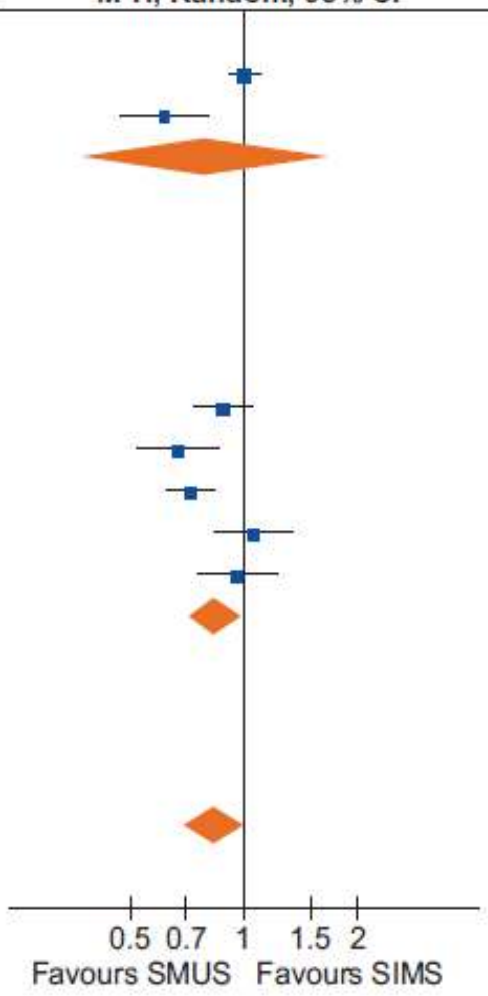
Single-Incision Mini-Slings Versus Standard Midurethral Slings in Surgical Management of Female Stress Urinary Incontinence: A Meta-Analysis of Effectiveness and Complications

Mohamed Abdel-Fattah [a,], John A. Ford [a], Chou Phay Lim [b], Priya Madhuvrata [c]*

SIMS vs. SMUS – **Patient Reported Outcomes**

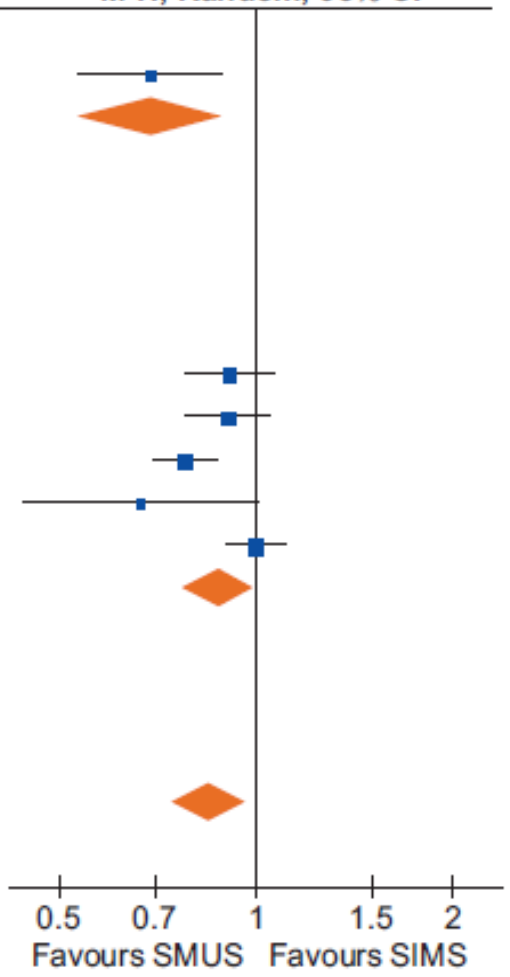
(a)

Study or Subgroup	SIMS Events	SIMS Total	SMUS Events	SMUS Total	Weight	Risk Ratio M-H, Random, 95% CI
1.1.2 SIMS vs RT-TVT						
Abdelwahab 2010	29	30	28	29	16.9%	1.00 [0.91, 1.10]
Basu 2010	22	37	32	33	12.5%	0.61 [0.47, 0.81]
Subtotal (95% CI)		**67**		**62**	**29.3%**	**0.79 [0.37, 1.67]**
Total events	51		60			
Heterogeneity: Tau² = 0.28; Chi² = 26.78, df = 1 (P < 0.00001); I² = 96%						
Test for overall effect: Z = 0.62 (P = 0.53)						
1.1.3 SIMS vs TO-TVT						
Djehdian 2010	25	29	15	15	15.1%	0.88 [0.74, 1.04]
Friedman 2010	26	42	39	42	13.1%	0.67 [0.52, 0.86]
Hinoul 2010	59	86	83	87	15.7%	0.72 [0.62, 0.84]
Kim 2010	18	20	17	20	13.5%	1.06 [0.84, 1.34]
Tommaselli 2010	28	37	30	38	13.2%	0.96 [0.75, 1.23]
Subtotal (95% CI)		**214**		**202**	**70.7%**	**0.84 [0.71, 0.99]**
Total events	156		184			
Heterogeneity: Tau² = 0.02; Chi² = 12.83, df = 4 (P = 0.01); I² = 69%						
Test for overall effect: Z = 2.10 (P = 0.04)						
Total (95% CI)		**281**		**264**	**100.0%**	**0.83 [0.70, 0.99]**
Total events	207		244			
Heterogeneity: Tau² = 0.05; Chi² = 39.15, df = 6 (P < 0.00001); I² = 85%						
Test for overall effect: Z = 2.03 (P = 0.04)						



SIMS vs. SMUS – **Objective Outcomes**

Study or Subgroup	SIMS Events	SIMS Total	SMUS Events	SMUS Total	Weight	Risk Ratio M-H, Random, 95% CI
2.1.2 SIMS vs RT-TVT						
Basu 2010	24	37	31	33	12.9%	0.69 [0.54, 0.89]
Subtotal (95% CI)		**37**		**33**	**12.9%**	**0.69 [0.54, 0.89]**
Total events	24		31			
Heterogeneity: Not applicable						
Test for overall effect: Z = 2.87 (P = 0.004)						
2.1.3 SIMS vs TO-TVT						
Djehdian 2010	26	29	15	15	18.4%	0.91 [0.78, 1.07]
Enzelsberger 2010	38	45	42	45	19.0%	0.90 [0.78, 1.05]
Hinoul 2010	67	86	87	87	21.1%	0.78 [0.70, 0.87]
Hota 2010	11	19	20	23	7.1%	0.67 [0.44, 1.01]
Tommaselli 2010	35	37	36	38	21.5%	1.00 [0.90, 1.11]
Subtotal (95% CI)		**216**		**208**	**87.1%**	**0.88 [0.77, 0.99]**
Total events	177		200			
Heterogeneity: $Tau^2 = 0.01$; $Chi^2 = 13.88$, df = 4 (P = 0.008); $I^2 = 71\%$						
Test for overall effect: Z = 2.04 (P = 0.04)						
Total (95% CI)		**253**		**241**	**100.0%**	**0.85 [0.74, 0.97]**
Total events	201		231			
Heterogeneity: $Tau^2 = 0.02$; $Chi^2 = 18.97$, df = 5 (P = 0.002); $I^2 = 74\%$						
Test for overall effect: Z = 2.49 (P = 0.01)						

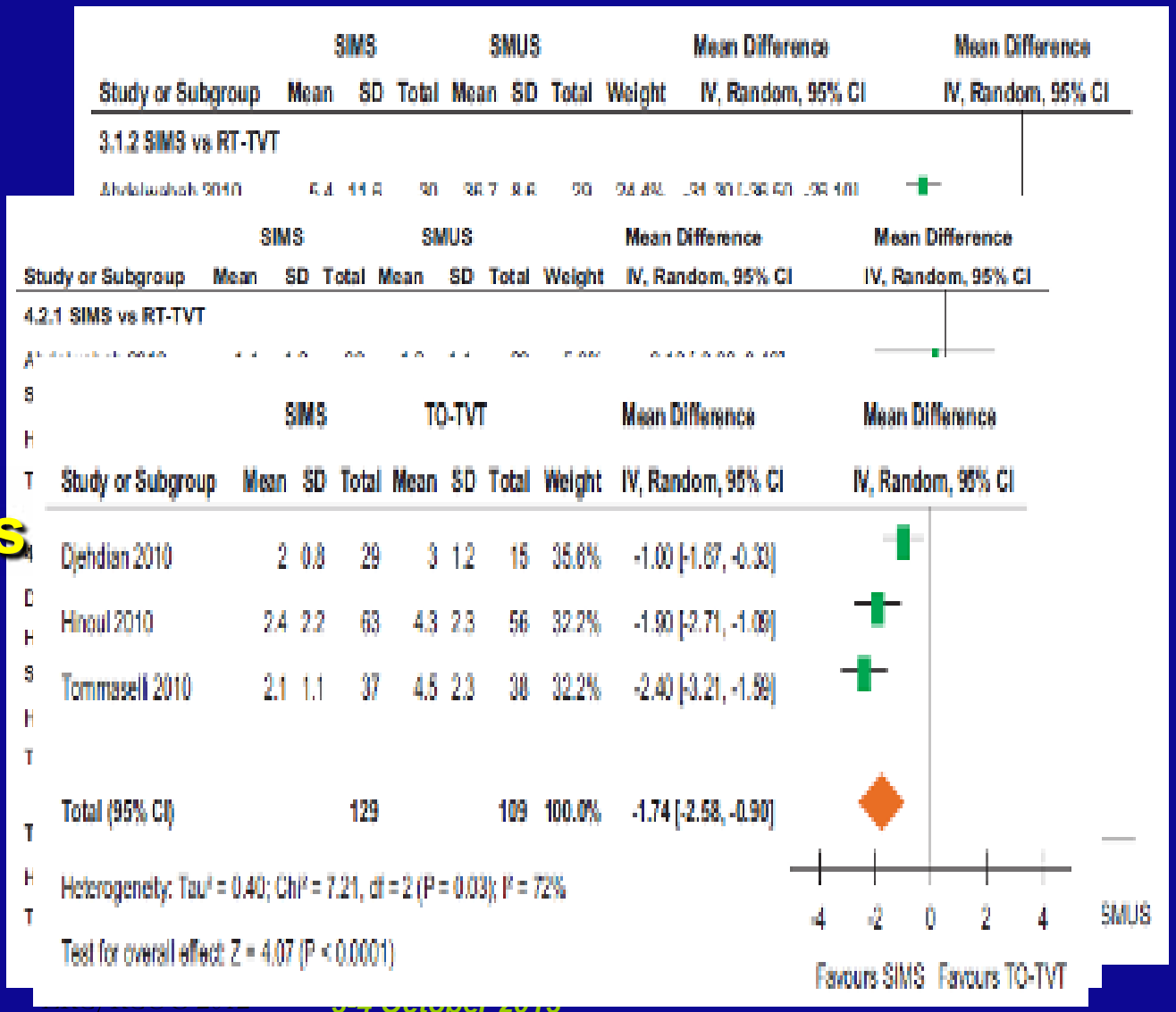


SIMS vs. SMUS – Operative Details

Operative Time

Hospital Stay

Pain Scores @Day 1



SIMS vs. SMUS – Conclusion

SIMS – Inferior

- Lower Patient-reported and objective cure rates at short term compared to SMUS: RR 0.83 95%CI 0.70, 0.99 and RR 0.85, 95%CI 0.74, 0.97 respectively).
-
- Repeat continence surgery (RR 6.72, 95%CI 2.39, 18.89) and *de novo* urgency incontinence (RR 2.08, 95%CI 1.01, 4.28) were significantly higher.

SIMS Better?

- Shorter operative time (WMD -8.67 minutes 95%CI -17.32, -0.02),
- Lower day-1 pain scores (WMD -1.74 95%CI -2.58, -0.09)
- Less post-operative groin pain (RR 0.18, 95%CI 0.04, 0.72

ARE MUS ABSOLUTELY SAFE ?

MAUDE Database (FDA)

	TVT	SPARC	TVT-O	ObTape	Monarc
AE (total)	700	66	1	149	12
Vascular	32 (2 death)	1	-	2 (1 death)	1
Intestinal	33 (6 death)	5	-	-	-
Bladder	40	6	-	-	-
Urathral	25	1	-	-	-
Nerve	10	1	-	-	-
Necrot.Fas	1	-	-	1	-
Abcess	0	-	-	2	-
Sepsis	0	-	1 (1 death)	2	-

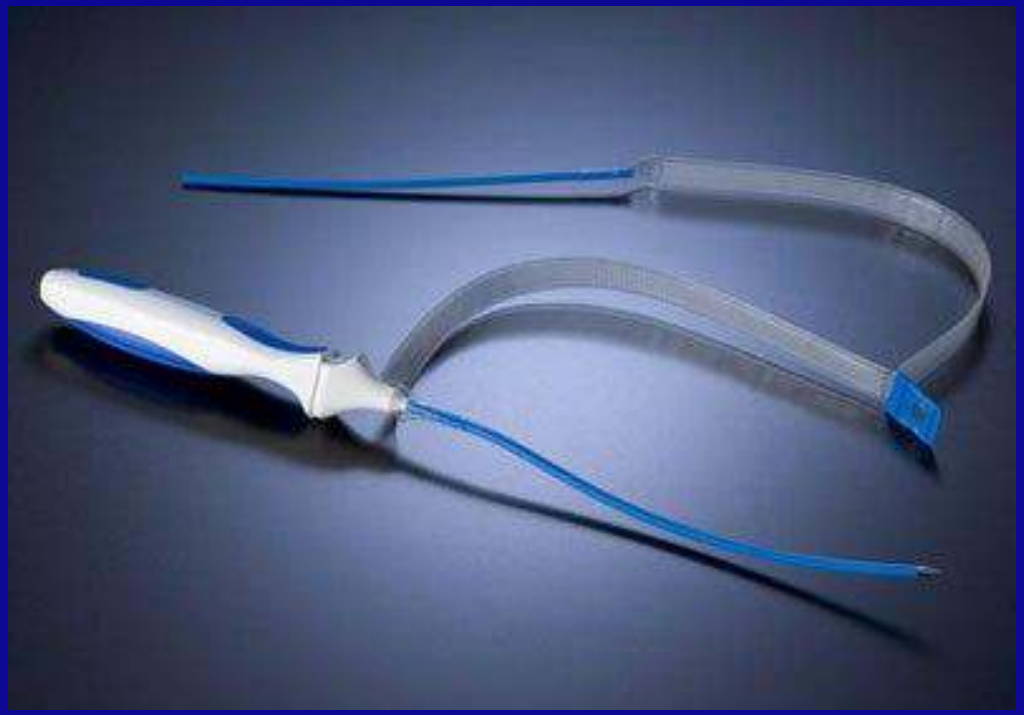
RP vs. OT SLINGS COMPLICATIONS (META-ANALYSIS)

	RP – SLINGS	TO – SLINGS
Bladder injuries	3.5%	0.2%
Pelvic hematoma	1.6%	0.08%
Groin pain (resolves 2 months postop)	1.5%	16%

1. SungVW et al., Am J Obstet Gynecol2007; 197: 3-11
2. Latthe PM et al., BJOG 2007; 114 (5):522-531
3. Novara G et al., Eur Urol.2008;53(2): 288-308

Stress Urinary Incontinence:
Advances of Surgical Management

PREFYX PPS™ SYSTEM



The Prefyx PPS Pre-pubic System is designed to improve safety, efficacy and procedure time.

Mediterranean & Gulf Urology Forum
Annual Meeting
3-4 October 2013

Stress Urinary Incontinence:
Advances of Surgical Management

PREFYX PPS™ SYSTEM





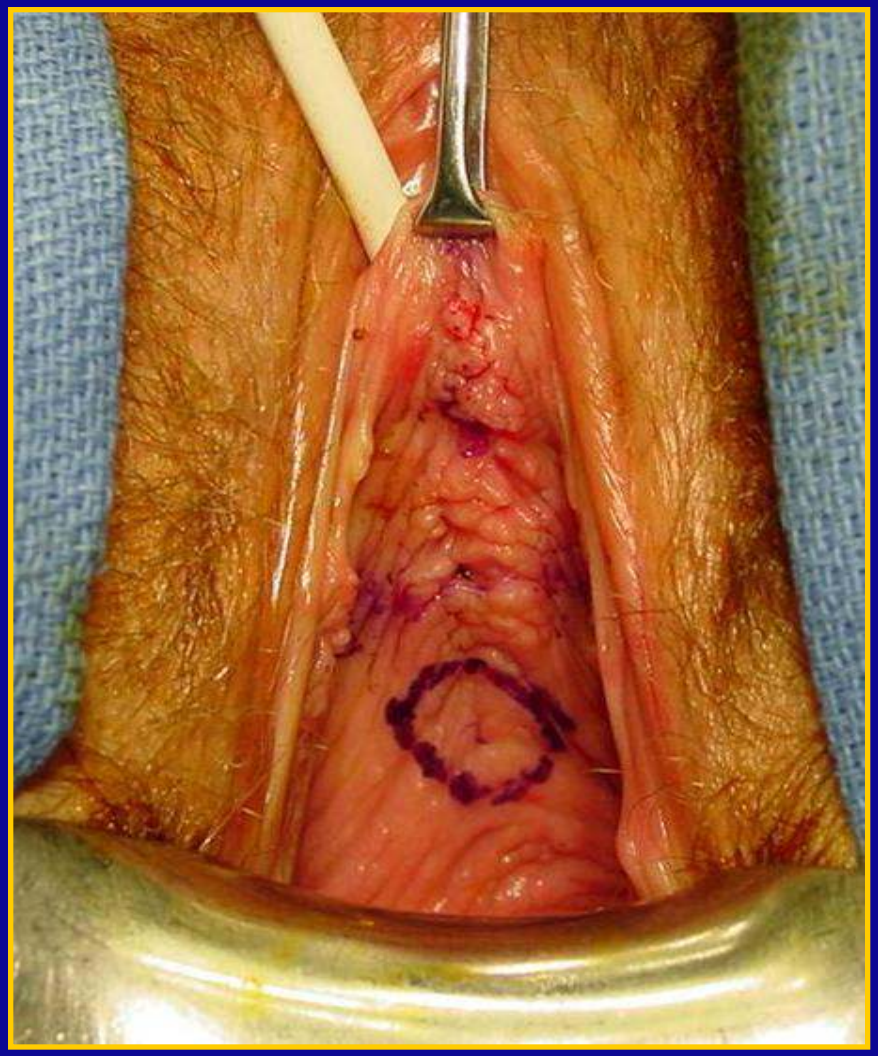
Placement of the sling that is outside the pelvic bowl potentially reduces the incidence of organ and vascular injury.

CONCLUSIONS

- TVT vs colposuspension
  - Objective cure rates of TVT with higher bladder perf risk
- TVT vs pubovaginal sling
  - Similar cure rates with higher retention and VD rate in PVS

CONCLUSIONS

- TVT vs TOT
  - Objective cure rates of TVT slightly higher than TOT, subjective cure rates were similar
  - TOT has less risk of bladder perf, blood loss, and de novo urgency



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CONCLUSIONS

- Mini slings are new and potentially important addition to anti-incontinence surgery- but what is the best suitable patient ???
- The heterogeneity in patient characteristics and outcome measures and lack of RCTs with long-term follow-up represent significant deficits for the evidence based data
- New devices will come into the market with great expectations no matter what …….