

1° Congresso Regionale Lombardia

Lodi 27-28 Marzo 2009



**Nuove frontiere della chirurgia
ginecologica mini-invasiva**

Quali sling / minisling

*Michele Meschia
Magenta*

Stress Urinary Incontinence

1997 AUA Clinical Guidelines

Procedures	Success rate
Anterior colporraphy:	61%
TSV needle suspensions:	67%
Retropubic suspensions:	84%
Sling procedures:	83%

Leach, J Urol 1997

Complications

A review

Sling

Burch

36 papers: 1771 pts

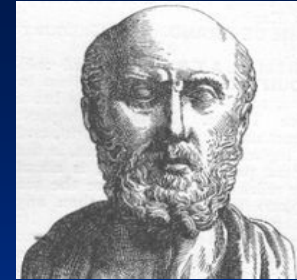
10 papers: 551 pts

Retention	11%	6%
D.I.	14%	5%
Cystotomy	6%	0.4%
Erosion	7%	0%
Fistula	4%	0%
New surgery	18%	0.4%

Ostergard, Int Urogynecol J 1997

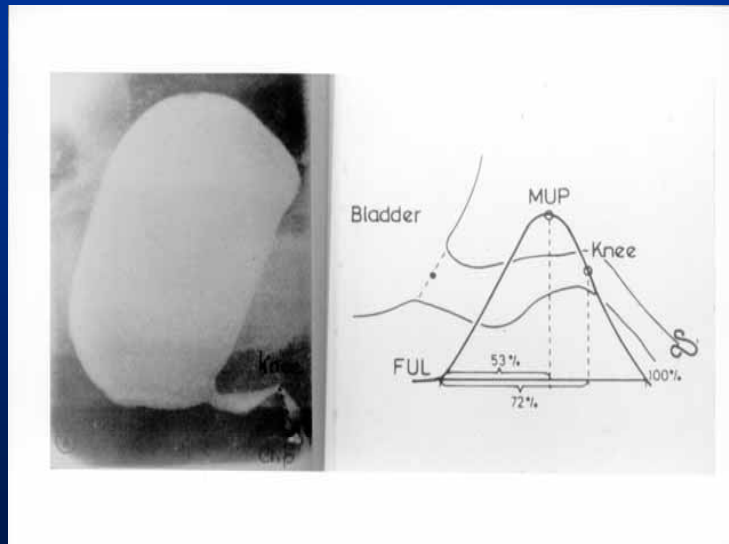
Hippocrates

(circa 450 BC)



- Before scientific progress will be accomplished on any subject, there must be:

‘Emancipation of the human mind from a servile adherence to prior opinions’



Westby M, Asmussen M, Ulmsten U.

Location of maximum intraurethral pressure related to urogenital diaphragm in the female subject as studied by simultaneous urethrocytometry and voiding urethrocytography.

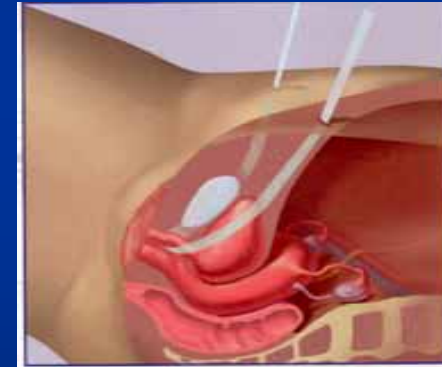
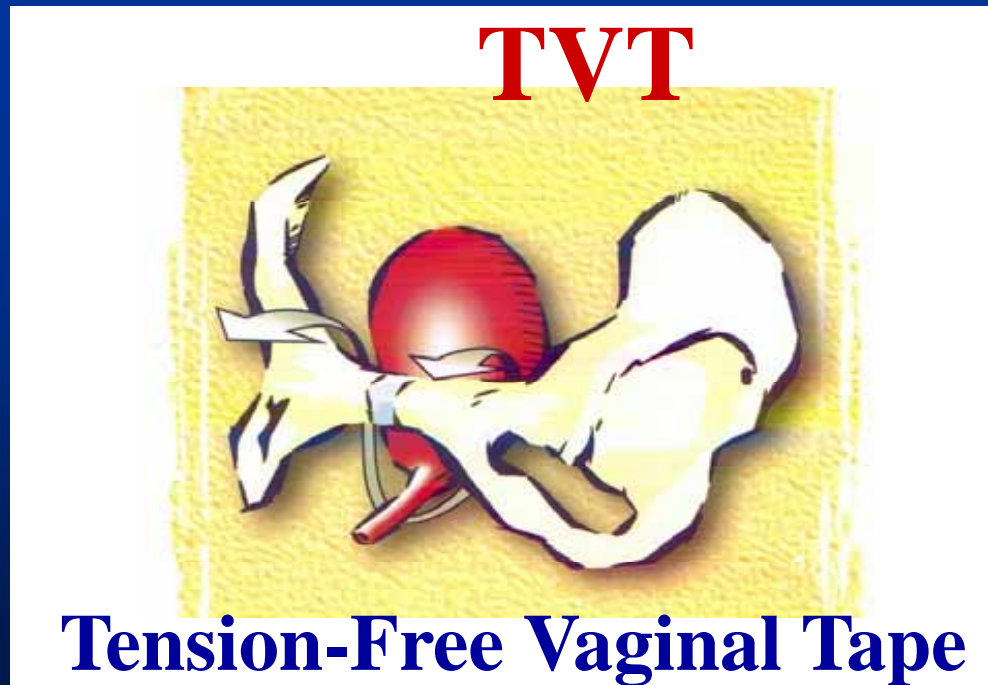
Am J Obstet Gynecol 1982;144:408-12.

Int Urogynecol J 1996; 7: 81-86

An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence

U. Ulmsten, L. Henriksson, P. Johnson and G. Varhos

- 75 pts with primary SUI (f.u. 2 years):
 - 84% cured
 - 8% significantly improved



TVT results: major observational studies

	Wang 1998	Ulmsten 1999	Olsson 1999	Meschia 2001	Jeffry 2001	Nilsson 2001
Patient number	70	50	53	404	112	85
Primary/secondary	primary	primary	both	both	both	primary
Anaesthetic	epi	LA	LA/epi	LA/epi	LA/epi	LA
Follow-up (mo.)	12	36	36	21	25	60
Subjective cure	87%	86%	90%	92%	66%	85%
Objective cure	83%	86%	90%	90%	89%	85%

Adapted from Atherton MJ, Stanton SL, BJOG 2005; 112:534-46

A prospective multicenter randomized trial of tension-free vaginal tape and colposuspension for primary urodynamic stress incontinence: Two-year follow-up

Ward K, Hilton P, Am J Obstet Gynecol 2004; 190:324-31

- 344 women with primary SUI
TVT: 175 Colposuspension: 169

Cure rates

	TVT (125)	Burch (101)
Subjective cure	79%	78%
Objective cure	81%	80%
Pts without f.u. → failures	63%	51%

Tension-free vaginal tape versus colposuspension for primary urodynamic stress incontinence: 5-year follow-up

Ward K, Hilton P, BJOG 2008; 115:226-33

- 344 women with primary SUI

	TVT (98)	Burch (79)
Neg. Pad test	81%	90%
Last control	75%	69%
De novo urg/UI	3%	9%
Cure of stress leak.	63%	70%
Satisfied	91%	90%

Eleven years prospective follow-up of the tension-free vaginal tape procedure for treatment of stress urinary incontinence

Nilsson CG, Palva K, Rezapour M, C Falconer Int Urogynecol J 2008; 19:1043-47

- 69 (77%) of the original 90 women have been evaluated

Negative stress test 95.3%

Negative pad test 90.2%

Negative both 90.2%

Outcomes

PGI

Cured 77%

Improved 20%

Failed 3%

Claiming dry 93%

TVT vs Burch

9 RCTs (Primary treatment)

TVT was followed by significantly higher continence rates compared to Burch colposuspension.

- Any definition of incontinence:
OR = 0.58; 95% CI 0.42-0.79: p = 0.0007)
- Negative stress test:
OR = 0.38; 95% CI 0.25-0.57: p < 0.0001)
- Negative pad test:
OR = 0.59; 95% CI 0.41-0.85: p = 0.005)

TVT and:

low pressure urethra

- Similar cure rates but more voiding problems
Liapis, Paick, Meschia

recurrent incontinence

- Equally effective
Lo, Kuuva, Rardin

mixed incontinence

- Lower cure rate declining with time
Paick, Holmgren

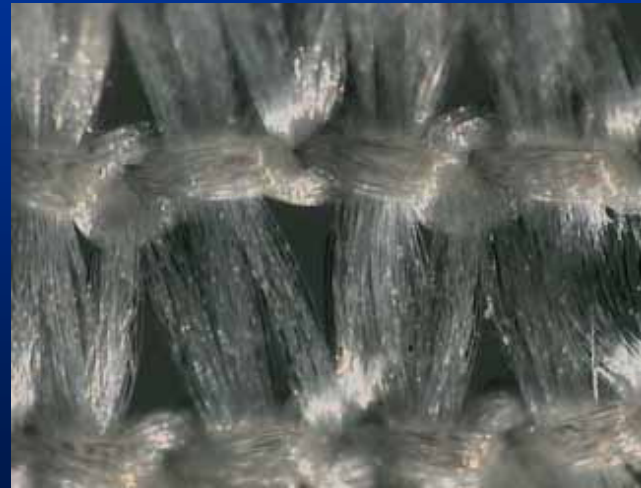
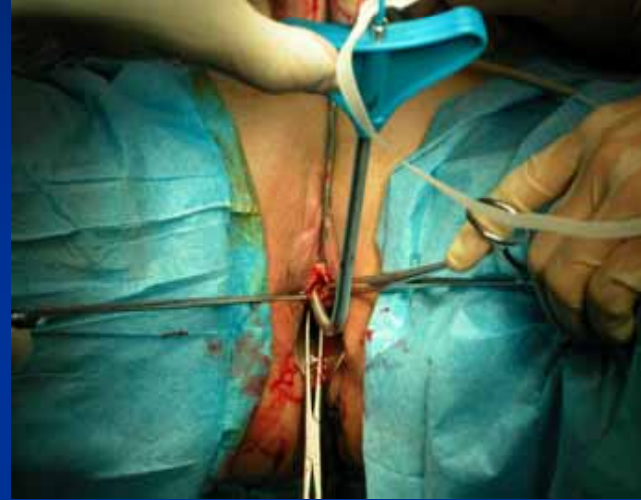
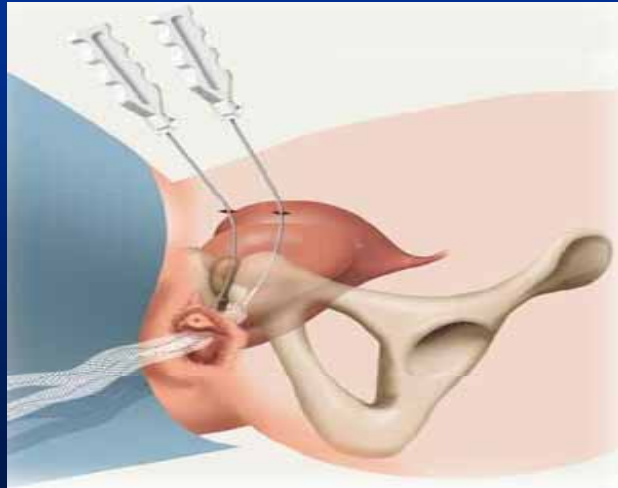
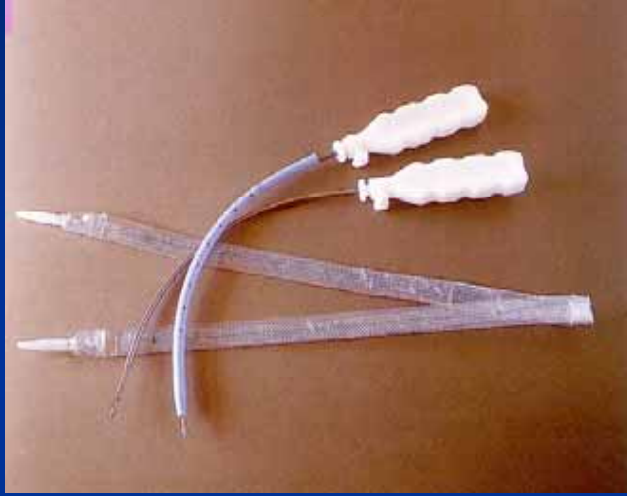
prolapse repair

- No difference in success rate and morbidity
- Contradictory results on voiding

Sokol, Meschia, DeTayrac

Other retropubic slings

Sparc



IVS Tunneler

TVT vs IVS

3 RCTs (primary treatment)

TVT outperformed IVS considering success rates according to:

- any definition of incontinence:
OR = 0.51 (95% CI 0.31-0.83; p = 0.007)
- negative stress test:
OR = 0.47 (95% CI 0.28-0.82; p = 0.007)
- subjective cure rates were similar:
OR = 0.63 (95% CI 0.37-1.09; p = 0.10)
- less erosion rate:
OR = 0.26 (95% CI 0.06-1.03; p = 0.06)

Novara et al, Eur Urol 2007, 2008

TVT vs Sparc

4 RCTs (primary treatment)

TVT outperformed Sparc considering results according to:

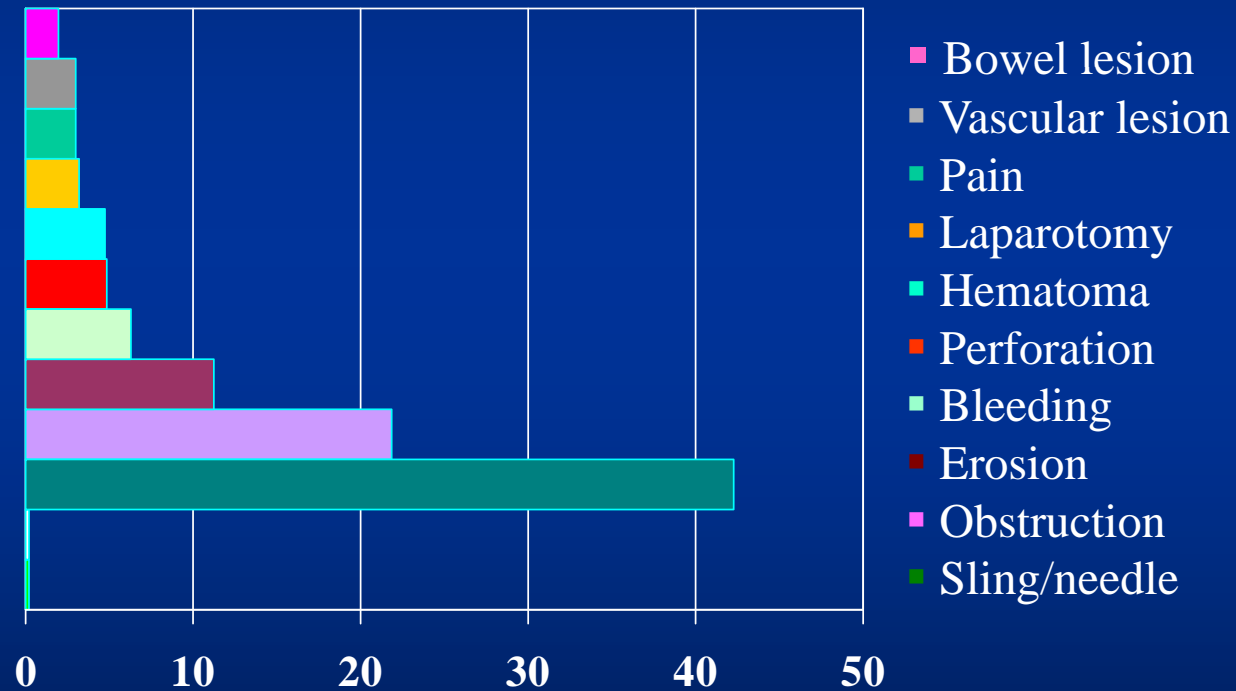
- subjective cure rate:
OR = 0.56 (95% CI 0.35-0.92; p = 0.02)
- objective cure rate (negative stress test or pad test):
OR = 0.53 (95% CI 0.34-0.82; p = 0.005)
- less common bladder perforation:
OR = 0.51 (95% CI 0.24-1.10; p = 0.08)

Novara et al, Eur Urol 2007, 2008

Complications with tension-free tapes (%)

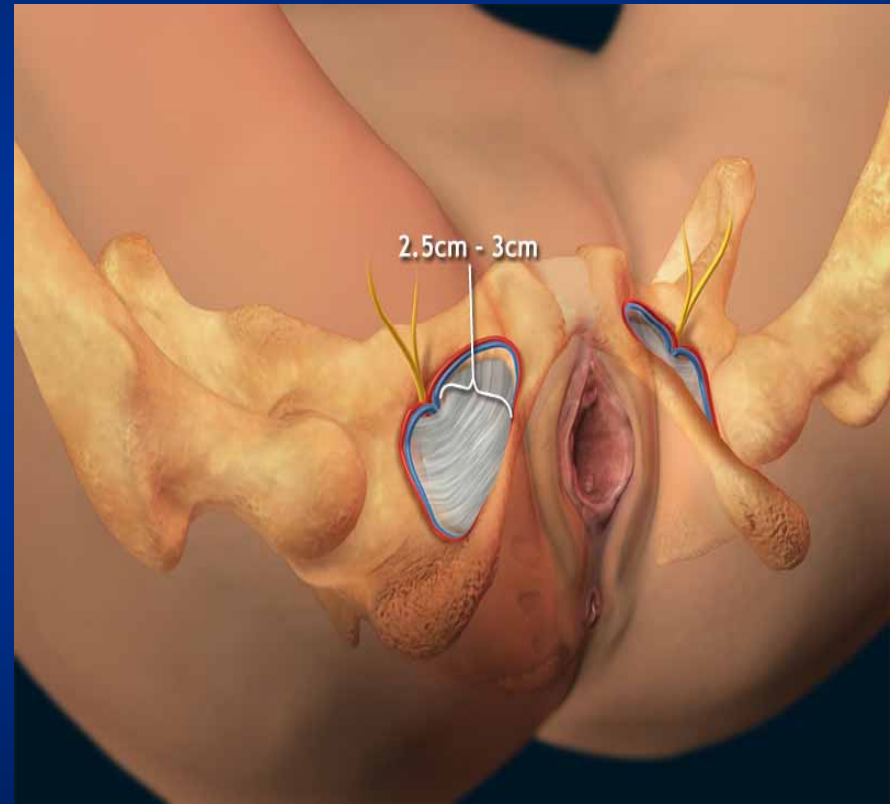
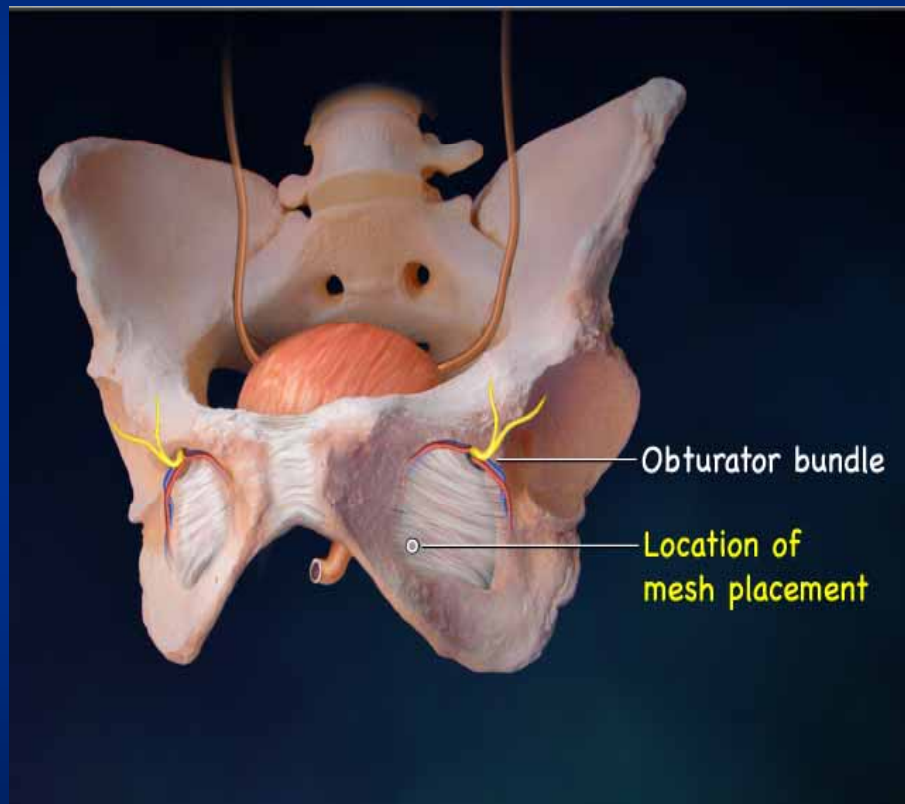
	Kuuva and Nilsson 2002	Tamussino 2001	Literature
Bladder perforation	3.7	3	1.1 - 11.1
Bleeding > 200 ml	1.9	2.3	05 - 17
Retropubic hematoma	1.9	1.9	0.8 - 3.3
Urethral lesion	0.07		
De novo urge	3.1		5 - 38.9
UTI	6.2	17	4.1 - 22.5
Obstruction	4.3	1.4	2.3 - 27

Complications with tension-free tapes Maude 1999-2002



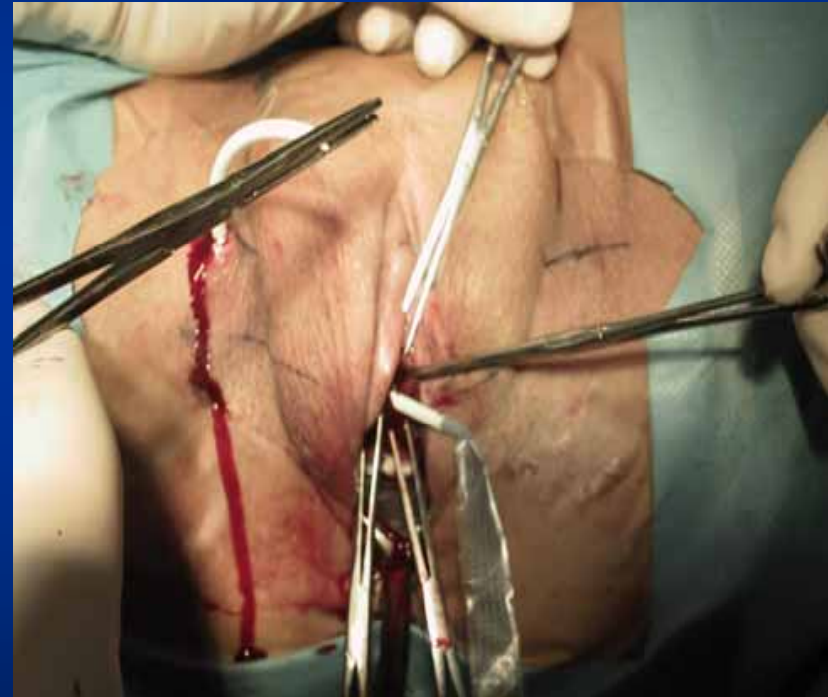
Maude: manufacturer and user facility device experience

Transobturator procedures (TOT)



Delorme, 2001

Tecniche out-in vs in-out



TOT results: observational studies

Author	n°	Device	f.u. mo.	Outcome
Mellier et al, 2004	61	Monarc	4	95% sub. cured
Costa et al, 2004	130	Uratape	7	83% ob. cured, 4% erosion
Spinosa, Dubuis, 2005	117	Obtape	16	92% sub. cured, 3% erosion
Roumeguere et al, 2005	120	Ura-Obtape	12	80% ob. cured, 3% erosion.
Waltregny et al, 2006	99	TVT-O	12	91% sub. cured, 4% release/section

Out-In vs In-Out:

➤ La tecnica Out-In garantisce un passaggio più lontano dal canale otturatorio

- 2.3 ± 0.4 vs 1.3 ± 0.4 cm, $p < .001$

Zahn et al, Obstet Gynecol 2007

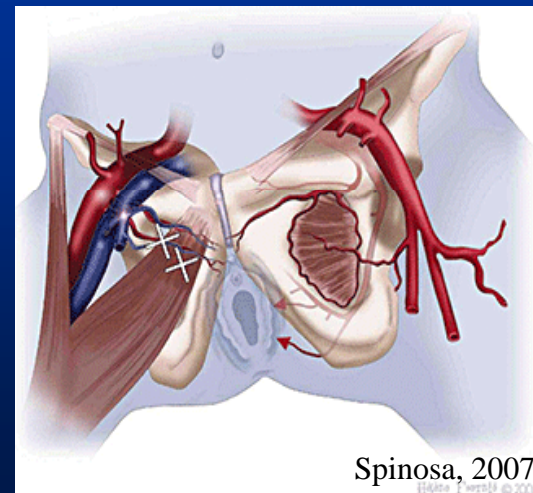
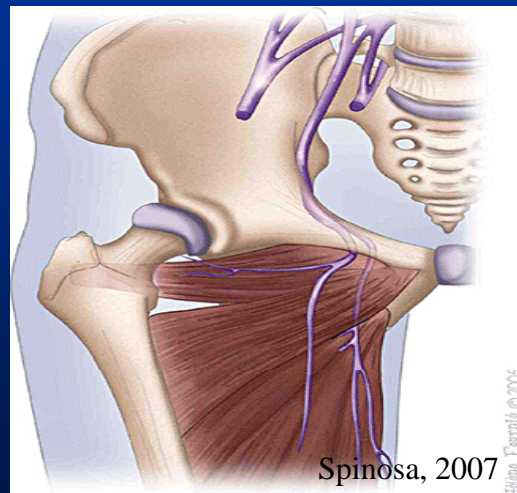
- 2.7 ± 0.4 vs 1.9 ± 0.3 cm, $p < 0.002$

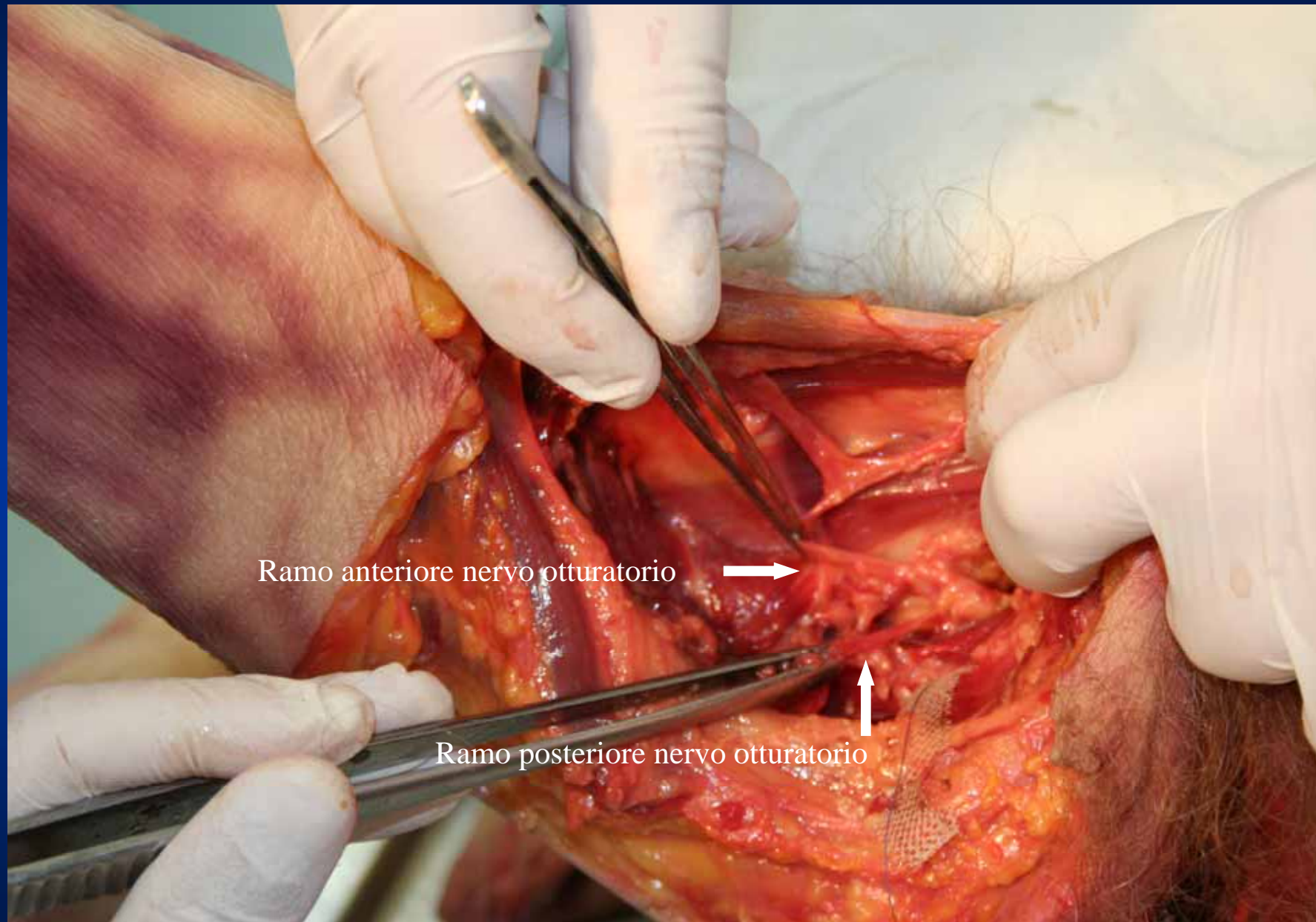
Acthari et al, Int Urogynecol J 2006

e più vicino alla branca ischio-pubica

0.04 ± 0.13 vs 0.39 ± 0.44 cm, $p = .008$

Zahn et al, Obstet Gynecol 2007





Ramo anteriore nervo otturatorio



Ramo posteriore nervo otturatorio



Outside-in vs Inside-out

RCTs

- *But et al, Int Urogynecol J 2008*

At 3 months → 88.7% vs 90.7%

Pain:

On discharge → 2.2% vs 2,6% ($p = 0.15$)

Duration (d) → 7.5 vs 21,6 ($p = 0.03$)

Intensity (0-3) → 1.3 vs 1.9 ($p = 0.000$)

- *Liapis et al, Int Urogynecol J 2008*

At 1 year → 90% vs 87%

Pain → 2% vs 5%

Complications by transobturator sling type

n = 173

	TVT-O	Monarc	Ob Tape
Erosion	1	4	98
Infection	2	1	22
Excess bleeding	3	1	1
Neuropathy	3	1	0
Bladder perforation	1	0	2
Urethral injury	3	0	0
Pain	8	1	0
Retention	5	1	1
Discharge	0	0	9
UTI	1	0	0

MAUDE database

Boyles, Int Urogyn J 2007

Comparison between TOT/TVT-O vs TVT Meta-analysis

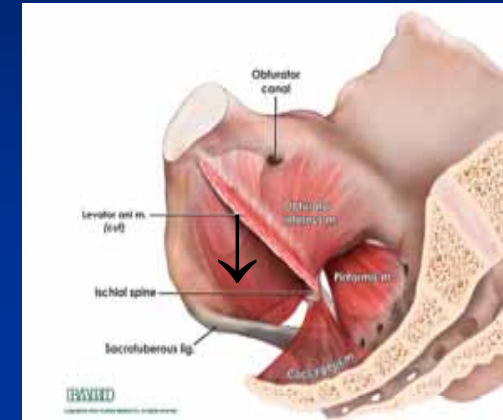
- Similar subjective cure rate:
OR = 0.85 (95% CI 0.60-1.25)
- Less common
bladder injuries: OR = 0.12 (95% CI 0.05-0.33)
voiding difficulties: OR = 0.55 (95% CI 0.31-0.98)
- More common
groin/thigh pain: OR = 8.28 (95% CI 2.7-25.4)
vaginal injuries or erosion: OR 1.96 (95% CI 0.87-4.39)

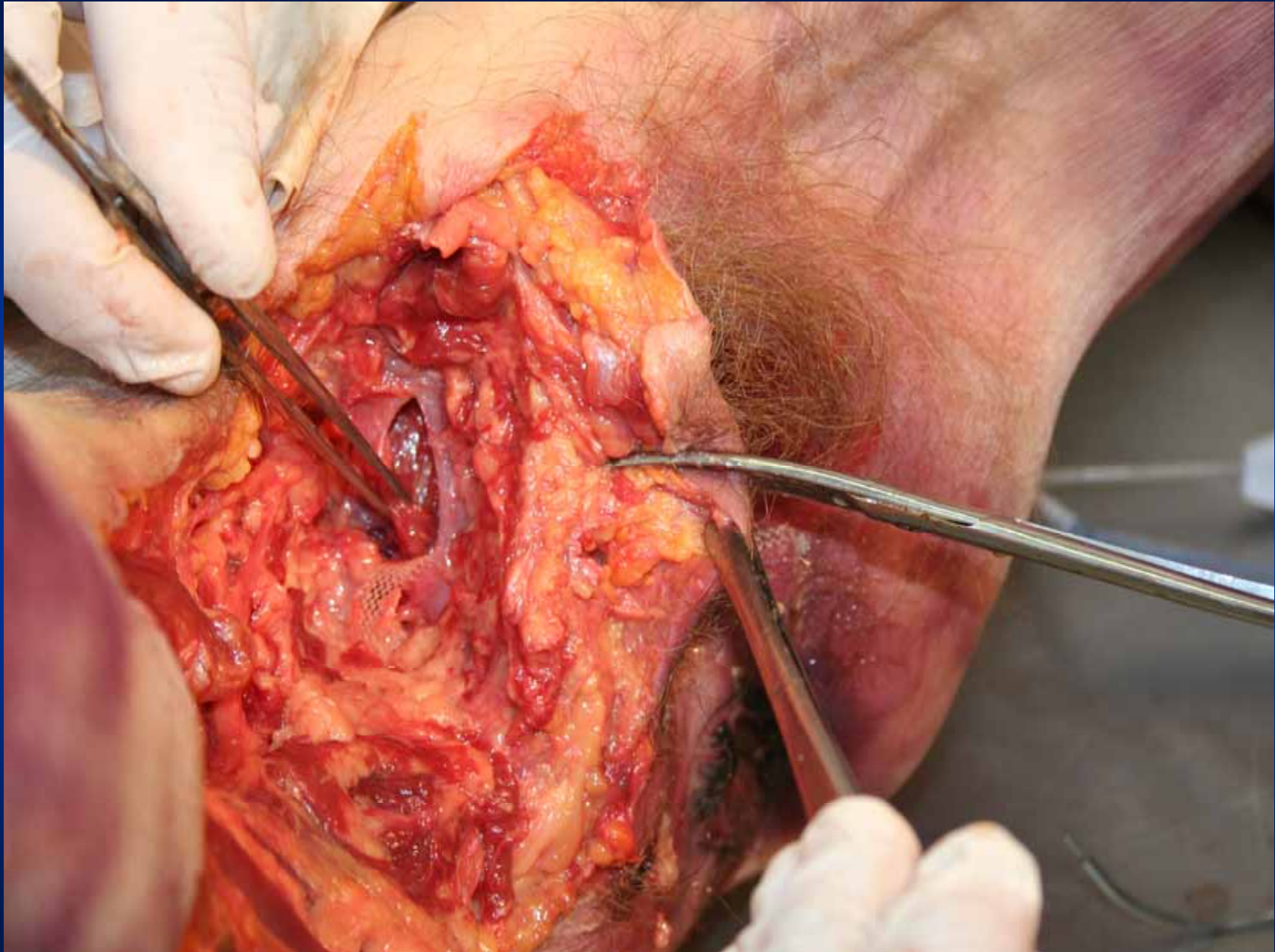
Latthe et al, BJOG 2007

New options

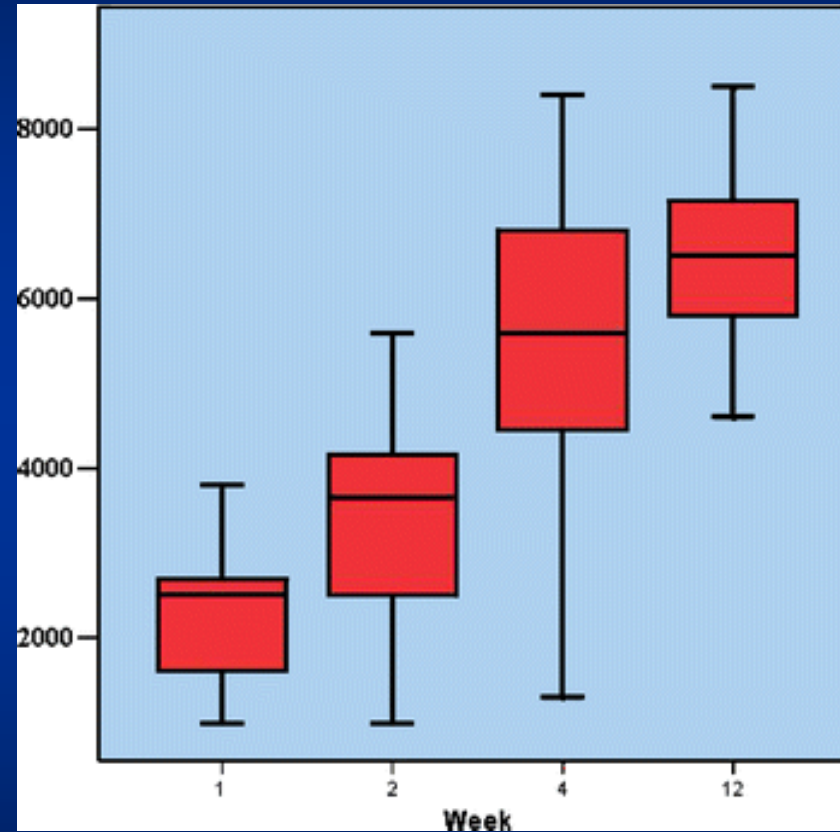
Single incision sling procedures

- fewer operative complications
- frequently performed on local anesthesia
- less post-operative pain
- day-case surgery





Mean pullout force of TVTx



The mean initial pullout values of TVT and TVTx were
 771 ± 291 vs 864 ± 331 ($p=0.86$)

Rezapour et al, Int Urogynecol J 2007

Single incision slings



Why would we prefer a new technique?

- New learning curve
- Happy with TVT / TOT / TVT-O
- What do I tell the patient? *Cure rate / Morbidity*

Pain

	Monarc	TVT-O	p
Pain on discharge (VAS score 0-10)	2.2	2.6	0.15
No. of analgesic (6 to 24 h after OP)	0.7	0.9	0.21
Days of post-op pain	7.5	21.6	0.033
Pain intensity (0-3)	1.3	1.9	0.0000
Success of treatment (VAS score 0-100)	88.7	90.7	0.96

Values are means

But et al, Int Urogyn J 2008

Results from a prospective on 95 patients receiving TVT-s for primary SUI

91 were available at a median follow-up time 12 months

Cure rates

Women without SUI symptoms	71 (78%)
Negative stress test	74 (81%)
ICIQ-SF (mean \pm SD)	4.4 \pm 5.7*
W-IPSS (mean \pm SD)	5.1 \pm 4.6**
PGI-I (mean \pm SD)	0.8 \pm 1.1

Complications

Voiding difficulty	7 (8%)
Urinary tract infection	9 (10%)
“De novo” urgency incontinence	9 (10%)
Defect healing	2 (2%)
New surgery	8 (9%)
Medical treatment	11 (12%)

* $p = 0.000$ and ** $p = 0.002$ when compared with pre-operative data

Meschia, *Int Urogyn J* 2009

Comparison with our previously published data

	TVT-s	TVT	TVT_O
Cure rates			
Subjective	78%	92%	87%
Objective	81%	92%	89%

- *TVT-s vs TVT: $p=0.04$*
- *TVT-s vs TVT-O: $p=0.25$*

Meschia et al, Int Urogynecol J 2007

Conclusions

Our data show that the TVT-s procedure is effective for the treatment of primary SUI with an highly significant improvement in incontinence related QoL.

Nevertheless a comparison with our own previously published data on TVT and TVT-O shows that TVT secur is associated, at the same follow-up time, with 10% lower success rate.

Meschia, Int Urogyn J 2009

Conclusions

- TVT is a long term efficacy procedure (Level 1)
- Comparison of TVT to TOT/TVT-O showed similar cure rates (Level 1)
- Comparison of TVT with other retropubic slings showed better outcomes for TVT (Level 2-3) but similar subjective cure rates (Level 2)
- New minimally invasive procedures need further evaluation with respect to efficacy and morbidity