Surgical Outcomes for Incontinence and Prolapse: 9th Annual Ob/Gyn Symposium

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Objectives

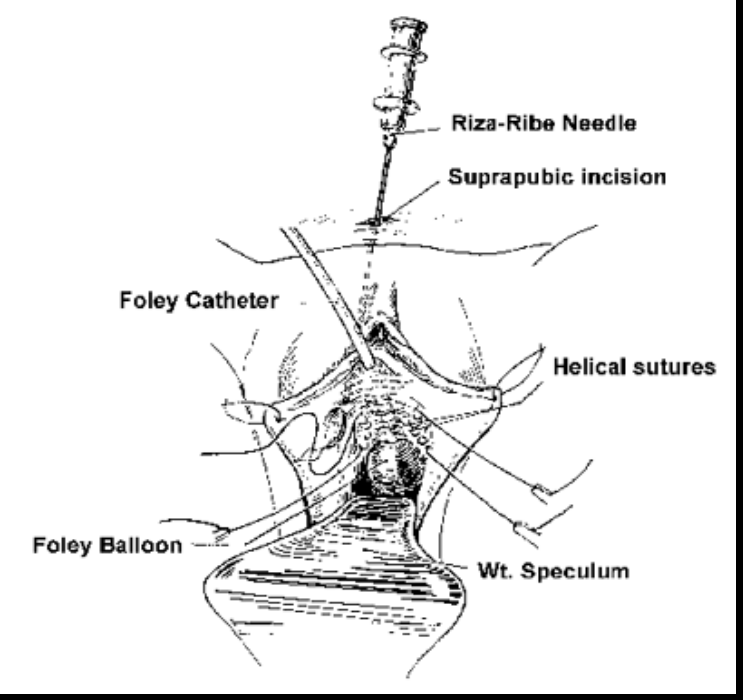
- Cite published success and complication rates for each continence procedure, quality of studies, and level of evidence
- Discuss differences in success rates of primary and secondary continence procedures and in the success rates in women with and without urethral hypermobility
- Discuss the alternatives, risks and benefits, complications, success rates, Traditional posterior repair and posterior repair with graft: apical repair with native tissues and with graft

Historical Perspective

The first pubovaginal sling using gracilis muscle around the urethra was performed by Von Giordano (1907)

Suburethral Kelly plication and anterior colporrhaphy originally described in 1913.

Virkud A. (2011) Best Pract Res Clin Obstet Gynaecol. 25(2):205-16.
Kelly HA (1913) Urol Cutan Rev. 1913; 17: 291.

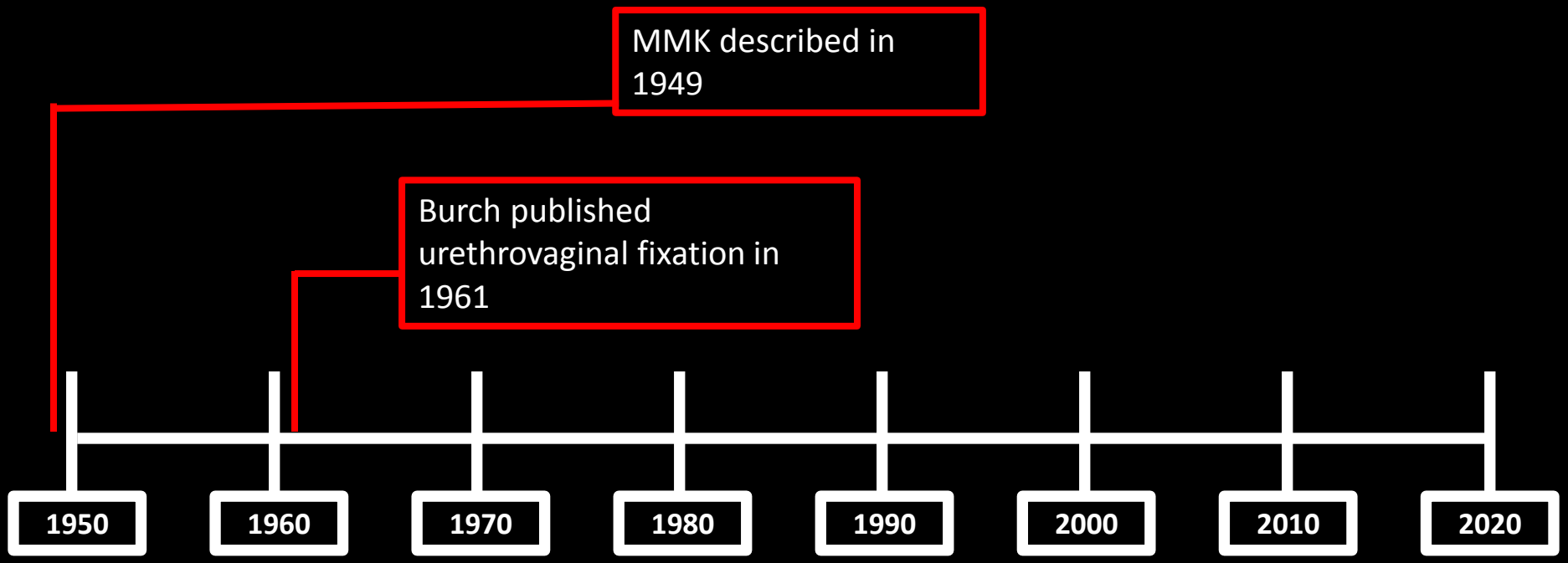


Pereyra (1959) described the 1st vaginal needle suspension method to treat SUI

1950 1960 1970 1980 1990 2000 2010 2020

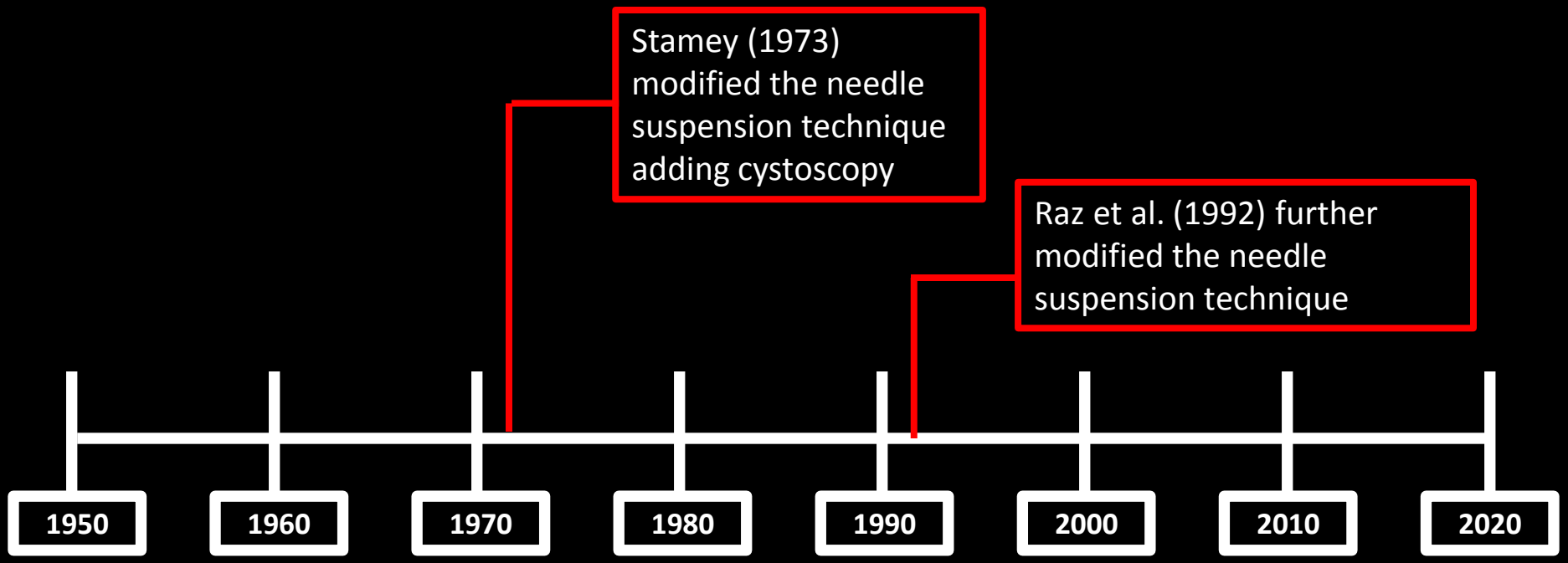
Barbalat Y and Tunuguntla H. (2012) Curr Urol Rep (2012) 13: 256-261.
Pereyra AJ (1959) West J Surg Obstet Gynecol; 67: 223-36.

- Open retropubic urethropexy procedures were also introduced for the treatment of stress urinary incontinence



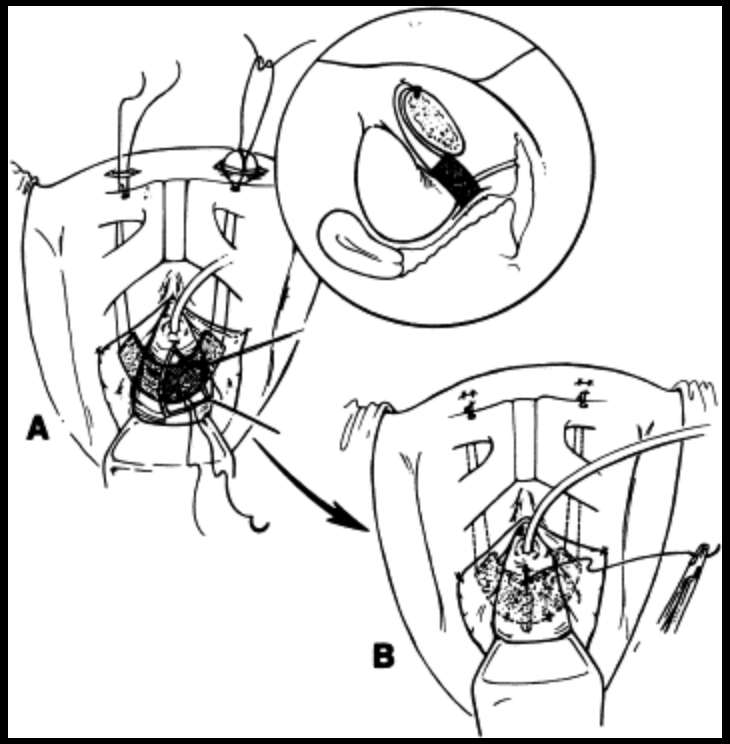
Marshall VF, Marchetti AA, Krantz KE. Sirg Gynecol Obstet 1949; 88: 509.
Burch (1961) Am J Obstet Gynecol; 81:281.

- Stamey performed the Pereyra procedure utilizing a single suture carrier with a vaginal incision and cystoscopy to protect the bladder

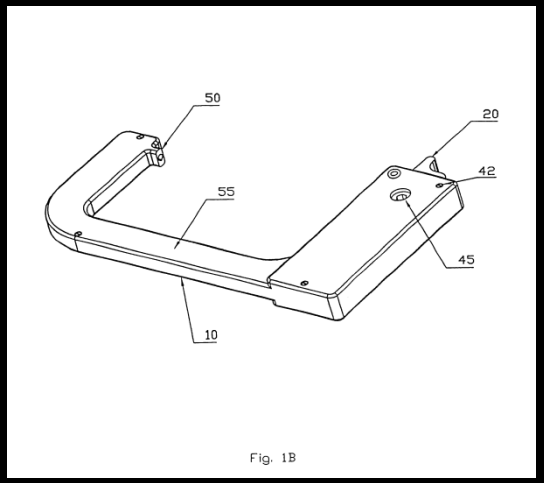


Stamey TA. (19730 Surg Gynecol Obstet ; 136: 547-54.
Raz S et al. J Urol 1992; 148: 845.

Vesica® Procedure



- Four perforations through the vaginal wall to produce a “Z” pattern of sutures in the vagina.
- Sutures were attached to bone anchors placed in the pubic bone.

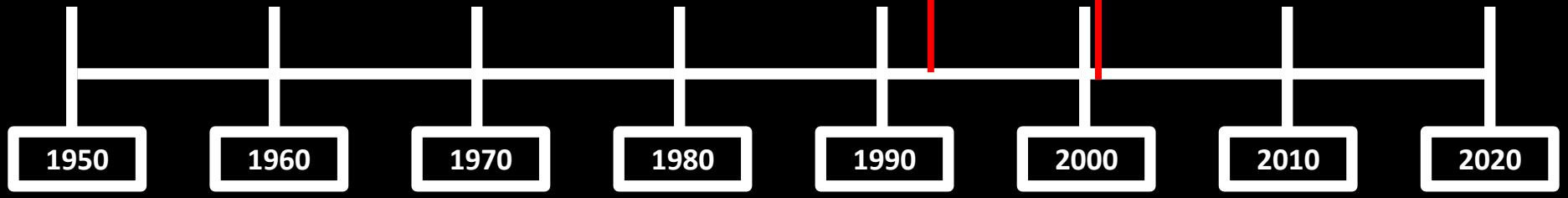


First pelvic reconstructive “procedure” marketed to the medical community

Benderev TV (1994) J Urol 152(6pt2): 2316-2320

Ulmsten and Petros (1993) describe intravaginal slingoplasty as a minimally invasive treatment for stress urinary incontinence in women.

Delorme (2001) described a transobturator
Suburethral sling to avoid complications of blind passage in the retropubic space



Ulmsten U and Petros P. Scand J Urol Nephrol. 1995 Mar;29(1):75-82. 10.
Delorme E. (2001) Prog Urol; 11: 1306-1313.

Rates of Surgical Cure as we knew it myth

- Anterior Colporrhaphy - 34 – 100% (average 60%)
- Retropubic Colposuspension - 68-97% (average 84%)
- Needle Urethropexy - 61-97% (average 88%)
- Pubovaginal Sling Procedure - 66-89% (average 81%)

Comparison of Postoperative Cure rates in Randomized Clinical Study of Anterior Colporraphy, Burch and Pereyra

- One of the first randomized trials for GSI but only 170 patients
- 82% AC, 84% Pereyra, 91% Burch (3mo)
- 65% AC, 72% Pereyra, 91% Burch (12 mo)

- Bergman et al Am J Obstet Gynecol 1989

AHCPR Review of Anterior Vaginal Repair

- 9 studies were reviewed – 1449 patients
- Overall cure rate was 62%
- Average complication rate was 14%
- Substantial variation among techniques, related to vaginal and bladder neck dissection

Burch Colposuspension Summary

- 2 sutures on each side of the bladder neck is better than 1
- Burch (and MMK) are more effective for SUI than paravaginal defect repair, Kelly plication, needle urethropexy
- Adding a hysterectomy does not alter the effectiveness of Burch
- Laparoscopic route is equal or slightly less effective than open route

Enter “Tension-Free” Vaginal Tape

Advantages of TVT

- May be performed under local (rarely is)
- Short operating time
- Outpatient procedure
- Tape is loosely placed, minimal anatomic distortion
- Decreased post operative voiding dysfunction

TVT Complications 1455 Pts in Finland

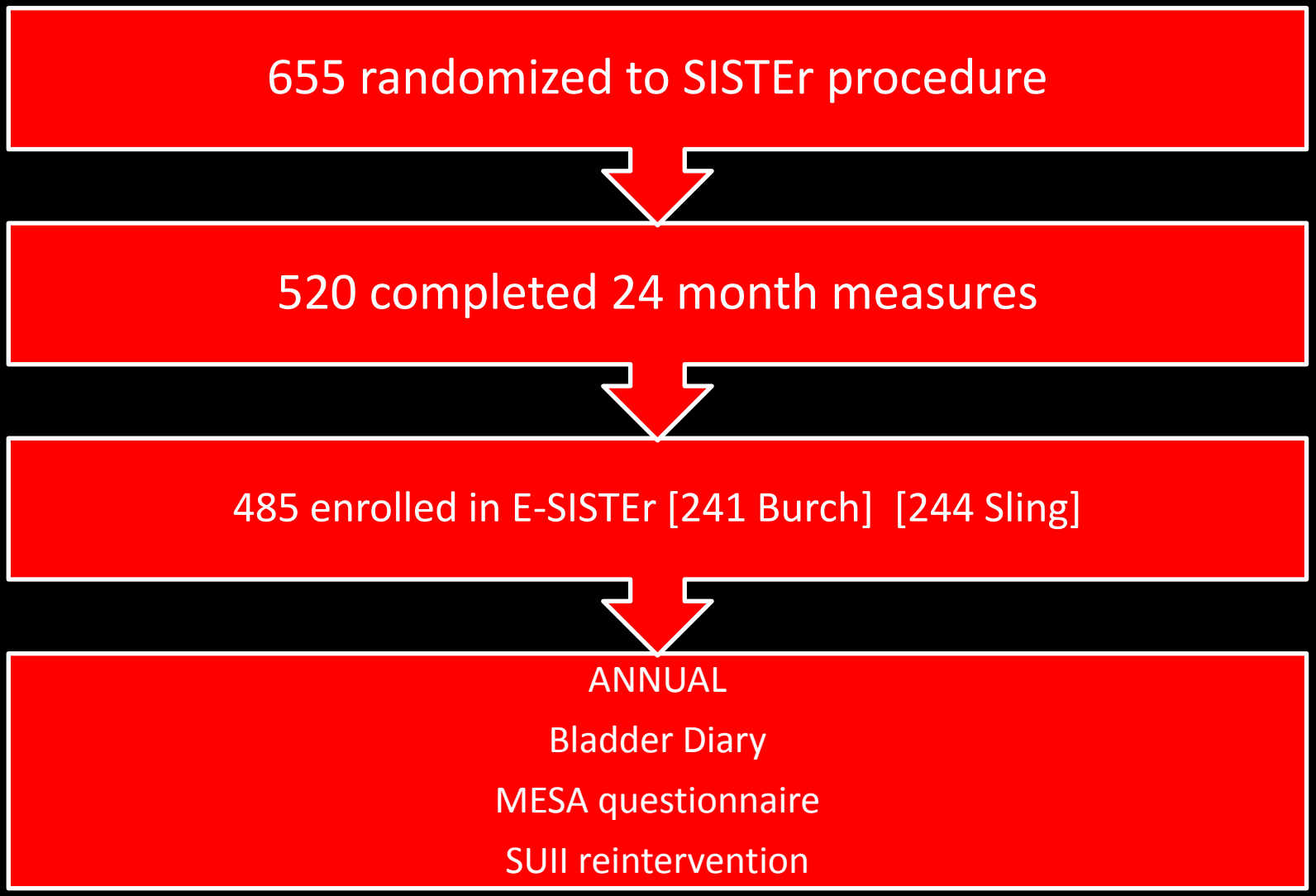
- Bladder Perforation 3.8%
- Minor voiding difficulty 7.6%
- Retention 2.3%
- Retropubic hematoma 1.9%
- Major Vessel injury 0.07%
- Need for post op laparotomy 0.3%

- Kuuva and Nilson 2002

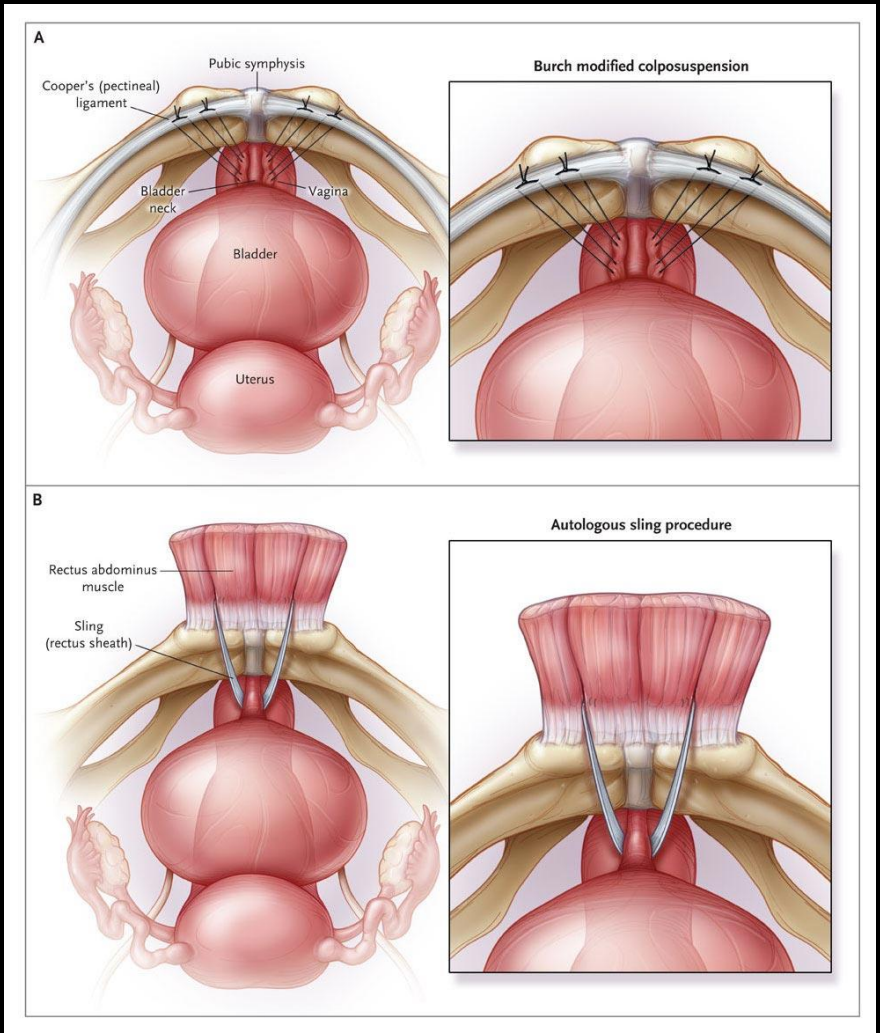
Prospective RCT Burch vs TVT for SUI

- 344 patients randomized from 14 centers in the United Kingdom
- no significant differences in cure rates after 6 months TVT-66%; Burch 57%
- longer voiding and recovery times with Burch
- bladder injury more common with TVT

Ward and Hilton 2002


655 randomized to SISTEr procedure
520 completed 24 month measures
485 enrolled in E-SISTEr [241 Burch] [244 Sling]
ANNUAL
Bladder Diary
MESA questionnaire
SUII reintervention

Burch Modified Colposuspension and Autologous Sling Procedure



Albo ME et al. N Engl J Med 2007;356:2143-2155

Albo et al (2007): Burch vs. Fascial Sling for SUI

- Multicenter NIH funded RCT with 655 women
- At 24 months , success rates for SUI were:
  - 66% for sling
  - 49% for Burch; P<0.001
- More women who had a sling had UTI, difficulty voiding, post op urge incontinence
- Serious adverse events were similar between groups
- Treatment satisfaction at 24 months was 86% for sling and 78% for Burch (p=.02)

UITN: SISTEr

- Fascial Sling vs. Burch in 655 women
- Results in NEJM 2007
- We learned:
  - High satisfaction rates with both
  - Sling more cures, but more voiding dysfx
  - No baseline UDS parameter assoc. with outcome

Albo et al. Burch Colposuspension versus Fascial Sling to Reduce Urinary Stress Incontinence. New England Journal of Medicine. 356(21):2143-2155, May 24, 2007

Overall continence at 2& 5 years using the E-SISTEr definition

Continence Rate	Burch (N=241)	Sling (N=244)
2 years* (95% CI)	43% (0.36, 0.49)	52% (N=244)
5 years** (95% CI)	24% (0.19, 0,30)	34% (0.28, 0.40)

* 2 year rate calculated using E-SISTEr definition from 454 women presenting for their 24 month SISTEr visit (229Burch) (225 Sling)
** 5 year rate calculated from 229 women in the Burch Group and 225 in the Sling group log rank test of equality of curves: Chi square =9.63 with p=0.002

Enter Trans Obturator Sling

TOMUS Methods

597 women
Stress predominant UI
+ cough Stress test

Preoperative UDS-Surgeon blinded to the results
Subjects randomized

Retropubic Midurethral Sling (RMUS)
Tension-free Vaginal Tape

Transobtubator Midurethral Sling (TMUS)
Gynecare or Monarc

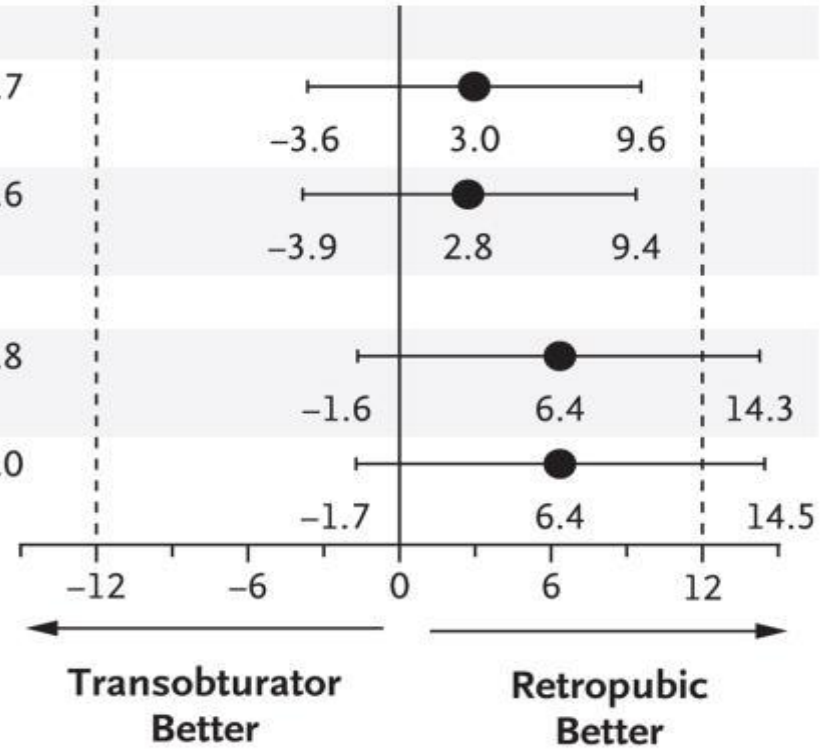
Concurrent non-mesh augmented vaginal surgery permitted

Post operative assessments

TOMUS 12 Month Results

- No differences in objective or subjective cure rates between transobturator approaches.
- No difference in patient satisfaction between groups, 85.9% RMUS vs 90% TMUS (p=0.14).
- No differences in changes in postoperative urinary symptoms, bother and impact on QOL across groups.

Model	Success Rate (%)		Difference in Rates of Treatment Success with 95% CI
	Retropubic sling	Transobturator sling	
Objective success			
Unadjusted	80.8	77.7	−3.6, 3.0, 9.6
With control for site	82.4	79.6	−3.9, 2.8, 9.4
Subjective success			
Unadjusted	62.2	55.8	−1.6, 6.4, 14.3
With control for site	62.4	56.0	−1.7, 6.4, 14.5



Richter HE et al, 2010

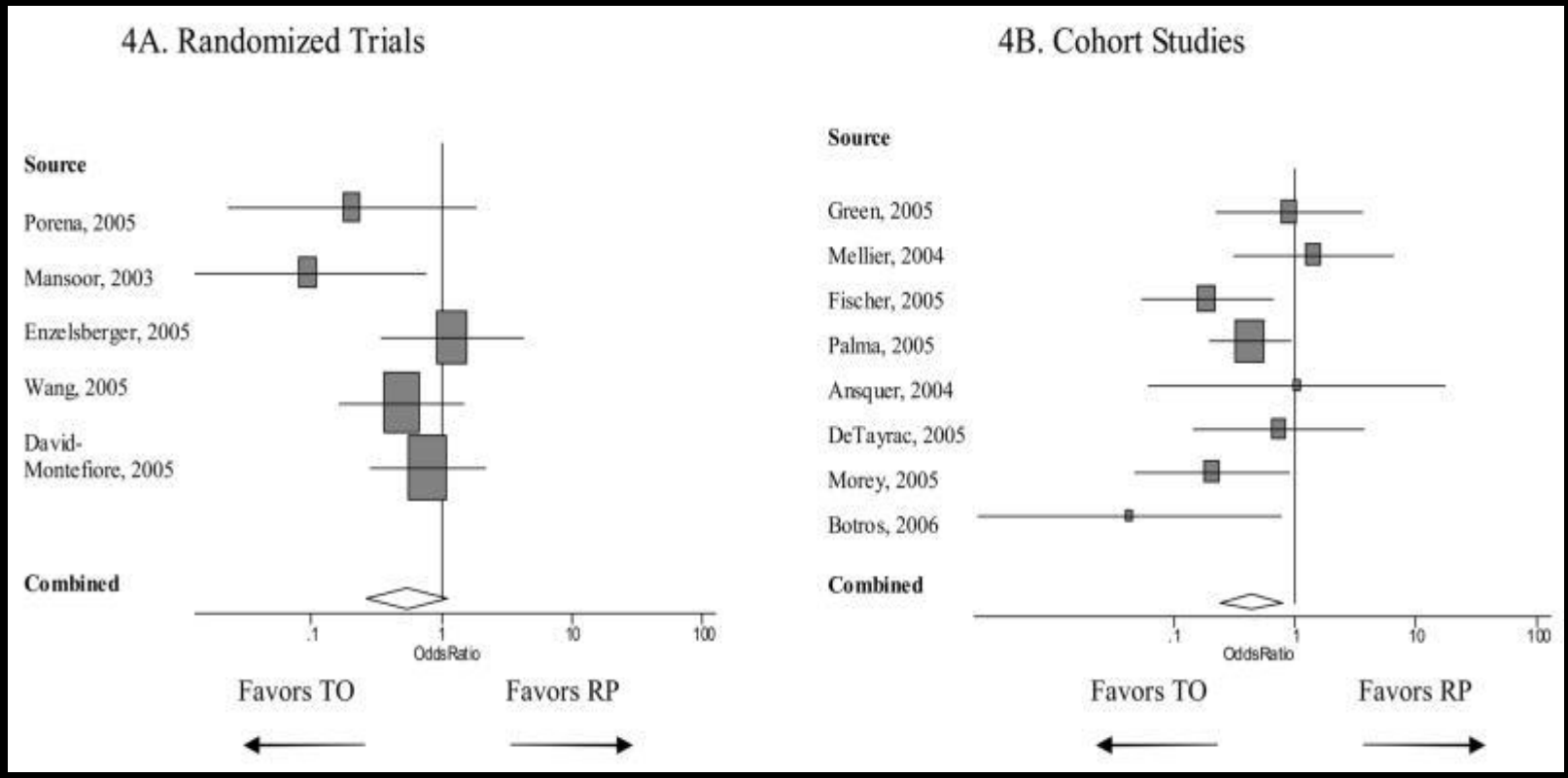
	TOT	TVT	p
Major Bleeding	4%	2%	.16
Retropubic hematoma	2%	1%	.44
Bladder Injury	0%	5.1%	.004
Bowel Injury	0%	0%	1.00
Nerve Injury	2%	1%	.44

Barber et al, 2008

	TOT	TVT	p
Leg Comp.	0.5%	0.5%	.89
Voiding Dys.	2.9%	8.9%	.01
Postop Anti-cholinergics	6.3%	14%	.05
UTI	7.4%	12.7%	.08
Mesh erosion	0.5%	1%	.99
Reop. for SUI	1.5%	2.4%	.51

Barber et al, 2008

Risk of Novo Irritative Voiding Symptoms After Transobturator vs. Retropubic Midurethral Slings



Sung VW et al 2007

Summary of TVT vs TOT trials

- Overall complication from both are low
- TOT has significantly lower injury rate than TVT
- TOT results in lower rates of voiding dysfunction and postoperative anticholinergic use than TVT
- Performance of concomitant surgery for prolapse does not increase voiding dysfunction or bladder injury

  - **Barber et al 2006** **Albo et al 2012**

Adverse Events after MUS Surgery for SUI TOMUS: Brubaker, 2011

- 42% of patients had some adverse event; 20% were classified as serious
- Intraoperative bladder perforation occurred in 5% of RP slings and 0% of TO slings ($P < .0001$)
- Voiding dysfunction requiring surgery occurred in 3% of RP slings and 0% of TO slings ($P = .002$); UTIs more common after RP slings
- Neurologic symptoms occurred in 5.0% of RP slings and 9.7% of TO slings ($P = .04$)

Potential Disadvantages of TOT

- Probably is less effective for recurrent SUI and for ISD patients
- Pain and infection in the genito-femoral folds and thigh; transient weakness in the upper leg
- There are rare cases of male sexual partners having penile pain and abrasions during intercourse from the woman's TOT sling

Success Rates of Secondary Continence Procedures

- Systematic review (Pradham 2011) of MUS for recurrent SUI suggested cure rates for RP TVT were significantly greater than for TOT
- **In RCTs by Rechberger (2009) and Schierlitz (2012), the long-term cure rates for RP TVT were significantly greater than for TOT in women with ISD**
- Data have suggested that Burch procedures and MUS have lower cure rates in women with non-mobile bladder neck.

Cochrane Review of Synthetic Slings (MUS)

- 62 trials; quality of evidence was moderate
- Synthetic MUS are as effective as fascial slings but with shorter OR time,, less voiding dysfunction and de novo urge
- Synthetic MUS are as effective as Burch
- RP bottom-to-top route is more effective than top-to-bottom route
- Monofilament tapes have higher cure rates and fewer erosions than multifilament tapes
- TO route was less favorable than RO route in objective cure (84%; RR 0.96; 17 trials; N=2434) although there was no difference in subjective cure rates.
- TO slings have less voiding dysfunction, blood loss, bladder perforations, and shorter operative times than RP slings.

The Mini-Slings

- Data are still too preliminary to comment on long term continence rates
- Complications, post-operative voiding problems and pain are all uncommon with mini-slings

CARE TRIAL: Abdominal Sacrocolpopexies with and without Burch

- In women with POP having ASC who were continent before surgery RPU decreased the rate of postoperative SUI (32% for RPU vs 45% no RPU)
- For women with the occult SUI on pre-testing , 37% had SUI after RPU 60% without RPU
- For women with no occult SUI on pretesting, 20% had SUI after Burch and 39% had SUI without Burch
- Women having abdominal sacral colpopexy should have an anti-incontinence procedure simultaneously to prevent occult SUI

- Brubaker et al 2006

The Dilemma

What should be done to the bladder neck in women with symptomatic prolapse having *vaginal* surgery who have no SUI on preoperative testing with reduction?

OPUS Trial

- In this multicenter RCT, 337 women without SUI but having vaginal surgery for POP were randomized to TVT or sham surgery
- The rate of UI at 12 months was 27.6% in the TVT group and 43.0% in the sham group (P= 0.002)
- 6.3 slings were placed to prevent 1 case of UI at 12 months
- UTI's bleeding complications (3.1%) and voiding disorders (3.7%) were all higher in the TVT group

Wei JT, et al 2012

Should reduction stress testing be used to decide if a sling should be done?

- Cohort study: 150 women had laparoscopic sacral colpopexy and followed 4-21 months
- Women with a (-) RST reduction stress test had sacral colpopexy only;
- Women with a (+) RST had sacral colpopexy and sling
- At follow-up 18.6% of women in the (-) RST group had a later sling for de novo SUI
- In the (+) RST group 7.3% had voiding difficulties requiring sling revisions
- Overall 88% of patients did not need a 2nd surgery

- Park J Int Urogynecol J 2012

Sling with Reconstructive Surgery (spoiler alert expert opinion)

- For patients with occult SUI having abdominal sacral colpopexy I choose TOT if robotic and Burch if open, unless I have more work to do vaginally then TOT

- For prolapse cases with occult SUI done vaginally I try to choose the MUS with the highest benefit and least side effects. My most common choice is a TOT unless I have established suspected ISD preoperatively.

- I usually choose a TOT over a TVT in this population especially for occult or prophylactic sling because of comparable cure rates less risk of urge and retention

Pelvic Organ Prolapse

- Major risk factors for pelvic organ prolapse:
  - age
  - vaginal parity
  - obesity
  - prior hysterectomy

Pelvic Organ Prolapse

- Lifetime risk of pelvic organ prolapse surgery is 7% by the age of 80
- Anterior vaginal prolapse is the most common and most likely to recur
- Repeat surgery for Prolapse or UI
  - 13% by 5 years, 29% over a lifetime

One in three patients will have recurrence for stress incontinence and POP.

What is a cure?

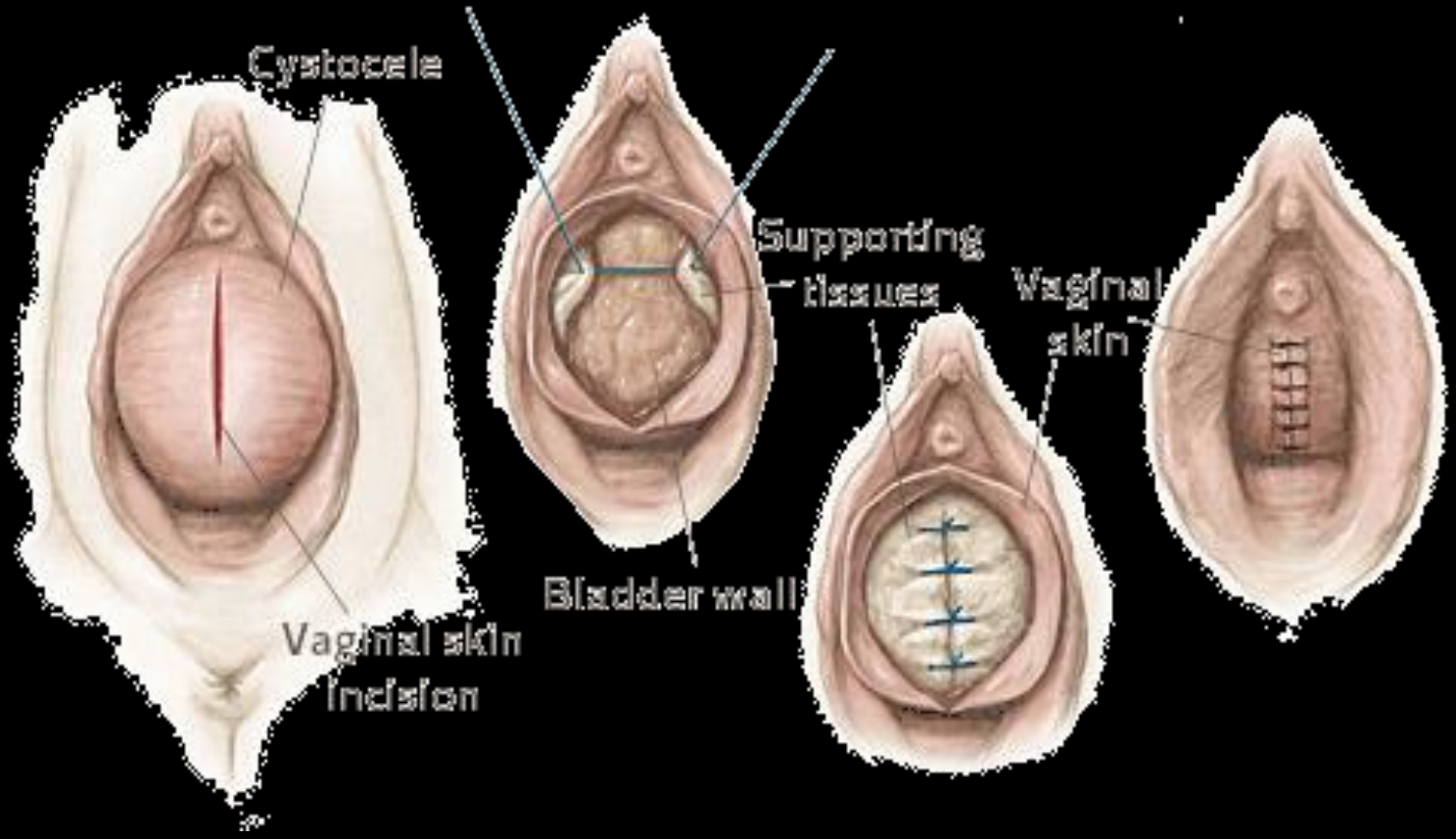
- We know that the hymen is the point for symptom development
- Pt complains when there is a bulge that can be seen or felt
- The absence of a vaginal bulge postoperatively has a significant relationship with the patient's assessment of treatment success and HRQOL
- Anatomic success alone does not correlate with health related quality of life

Swift et al 2000

Bradley et al 2005

Barber et al 2010

Traditional Anterior Repair



Why grafts?

- Extrapolating from surgical success with hernia and success of TVT
- Grafts will improve the function of the repair
- Make the repair more durable
- Decreases operative time and improved return to function

Biological Grafts

Autologous (pts own tissue)

- Increase morbidity / hernia

*Allograft (postmortem tissue bank)** cadaveric fascia lata, dura

- Durability / prion

*Xenograph (animal derived)** Porcine dermis (Pelvicol), Porcine small intestine submucosa (SIS), bovine pericardium.

*small risk prion / virus ½ million

Native Tissue Colporraphy vs Biologics

- Any biological graft to AC: objective failure rate AC 25% versus 14% RR 1.77(1.20,2.63)
- Subjective: no benefit demonstrated
- Compared to native tissue:

Porcine dermis; conflicting findings:

Meschia 2007 93% graft vs. 81% native

Hviid 2010 93% graft vs 85% native

Menafee 2011 86% ppmesh 55% dermis 52% native

Feldner 2010 SIS benficial 86% SIS vs 67% native

Guerette 2009 bovine pericardium 77% vs 63% native but no difference

Anterior Colporrhaphy vs. Transvaginal Mesh for POP

- Multicenter RCT, N=389
- Stage 2 anterior POP
- Anterior Colporrhaphy versus Anterior Prolift
- Primary outcome (assessed at 12 months)
  - POPQ stage 0-1
  - absence of vaginal bulge symptoms
  - no other pop surgery performed
    - Altman NEJM 2011

Anterior Colporrhaphy vs. Transvaginal Mesh for POP

- Primary outcome: Mesh 60.8% vs AC 34.5%
  p<.001 RR 3.6 95%CI 2.2-5.9
- Anterior mesh associated with:
  - greater OR time (20 min) and blood loss (50 cc)
  - more post op SUI : 12.3% vs. 6.3% p=.05
  - increase bladder perforations: 3.5% to 0.5% p=0.07
  - 3.2% risk of mesh exposure
  - no difference in sexual function

Anterior Colporrhaphy vs. Transvaginal Mesh for POP

- Quality-of-life questionnaires: no difference
- Reoperation rate POP 1.3 vs. 3%
  RR 2.28 95% CI 0.93 to 5.10
- Mesh **decr** objective failure rate 14 vs. 49%
  RR 3.50 95% CI 2.71 to 4.52
- Mesh **decr** subjective failure rate 17 vs. 28%
  RR 1.62 95% CI 1.22 to 2.14

Maher Cochrane 2012

Anterior Colporrhaphy vs. Transvaginal Mesh for POP

- AC **decr.** de novo prolapse in apical and posterior compartment 9.5% vs. 17.7%
  RR 0.49; CI 0.25-.97
- Mesh erosion 10.4%
- Surgery for mesh erosion 6.3%
- Mesh associated with increased OR time and blood loss
- Mesh tendency towards greater cystotomy rate and de novo SUI

Maher Cochrane 2012

The evidence as we know it in 55 minutes

Thank you.