ICS Lecture

Meshes for POP surgery
Official statements and legal situation in 2019

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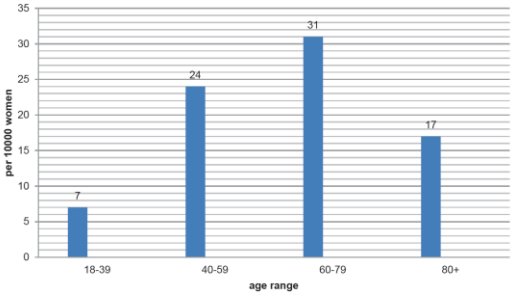
Disclosures

In the last two years I have been investigator, trainer, speaker or consultant for:

Astellas, Boston Scientific, Contura, Gebro, Lacer, Medtronic, Neomedic, Pfizer, Pierre Fabre

Pelvic Organ Prolapse

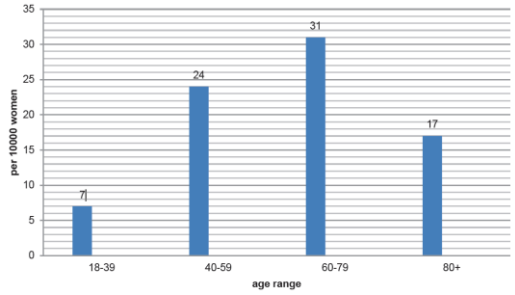
- POP in > 50% of women over 50
- Women > 65 is the fastest growing segment of the population
- 11.1% lifetime risk of surgical intervention
- Surgery for POP is much more common than continence surgery
- Often performed with continence procedures
- Most commonly performed vaginally



% Women with POP seeking care

Location of POP

Anterior only	**40%**
Anterior and apex	20%
Posterior only	7%
Posterior and apex	10%
All three compartments	18%
Anterior compartment involved	**78%**
Highest failure in anterior compartment	**30-70%**



Adapted from Incontinence ICI 2017, 6th Edition

Shows the surgical treatment for POP/ rate per 10000 women (2003)

Do we need to treat all POP?

- 40% women without symptoms of POP undergoing annual gynaecologic exam have descent of the anterior vaginal wall to within
  1cm o f hymen
- Decision to treat should be based on symptoms
  - "You cannot make an asymptomatic woman feel better, but you can make her feel worse"
- Exceptions - severe POP with **hydronephrosis** or vaginal/cervical erosion

Usually occurs with uterine prolapse
Not a result of urinary retention, but rather kinking of the ureters
Resolves with reduction of the prolapse
All women with stage III-IV uterine prolapse who elect no treatment should have a renal ultrasound

Adapted from Incontinence ICI 2017, 6th Edition

The Standardization of Terminology for Researchers in Female Pelvic Floor Disorders

A. M. Weber[1], P. Abrams[2], L. Brubaker[3], G. Cundiff[4], G. Davis[5], R. R. Dmochowski[6], J. Fischer[7], T. Hull[8], I. Nygaard[9] and A. C. Weidner[10]

2001 NIH Workshop on Standardization of Terminology for Researchers in Pelvic Floor Disorders

Am J Obstet Gynecol 2001; 185: 1299-306

Measuring the Success of POP Repair Based on Anatomy

Recurrent descent of the anterior vaginal wall to within 1 cm of the hymeneal ring = recurrence

Three techniques of anterior colporrhaphy

- Success based exclusively on anatomic outcome
- Success = points Aa and Ba ≤-2 and improved

At 23 months f/u recurrence occurred in:

- 70% of the traditional anterior colporrhaphy
- 54% of the "ultralateral" anterior colporrhaphy
- 58% of the absorbable mesh-augmented colporrhaphy
- Most patients were asymptomatic

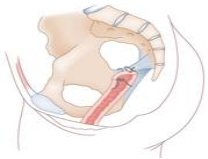
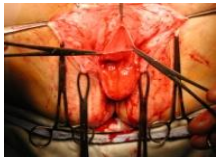
40% of normal women without symptoms of POP would not meet the definition of "satisfactory" anatomic outcome
75% of normal women who have annual gynecologic examinations without symptoms of POP would not meet the definition of "optimal" anatomic outcome

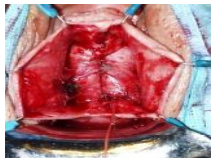
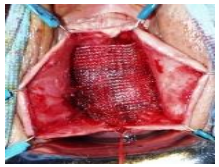
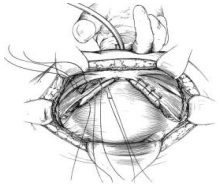
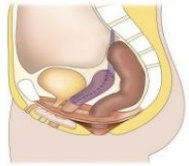
2009 NICHD Pelvic Floor Disorders Network
(National Institute of Child Health and Human Development)
Barber MD, Burbaker L, Nygaard I, Wheeler TL, Schaffer J et al. Defining Success After Surgery for Pelvic Organ Prolapse. Obstet Gynecol 2009;114(3):600-9.

- **Any definition of success after POP surgery should include the absence of bulge symptoms plus anatomic criteria and the absence of retreatment**
- **The use of the hymen as a threshold for anatomic success seems a reasonable and defensible approach**

There is More Than One Approach to Correct POP

- **Vaginal approach**
  - Ileococcygeus vaginal vault suspension
    - Manchester operation
    - McCall Culdoplasty
    - Colpocleisis procedures
    - Sacrospinous Ligament fixation
    - Uterosacral vaginal vault suspension
  - Anterior wall prolapse repair
    - Anterior Colporrhaphy
    - Paravaginal repair
    - Graft augmentation
  - Posterior wall prolapse repair
    - Posterior Colporrhaphy
    - Graft augmentation
- **Abdominal approach**
  - Paravaginal repair
  - Halban
  - Moschcowitz
  - Sacrocolpopexy

POP Questions

The Goals of Surgery are to Relieve Symptoms and Restore/Preserve Function!

- What are the indications for surgery?

  Only symptomatic POP stage II or Ba = 0+

- Should the uterus be removed?

  No need if normal, protection effect in SCPX

- What is the best route for surgery?

  Abdominal & vaginal relatively equivalent. Abdominal higher morbidity.

- How to manage the bladder outlet?

  Need to balance risk of SUI vs overtreatment & related complications

- **Should we use meshes? If yes, when?**

Mesh seem to improve the anatomic outcome but with a higher complication rate

Author	Year	Type	No	Review (Months)	Success Rate (%)	Complication
Vollebregt [105]	2011	RCT polypropylene Avulta Bard Vicryl AC	56 58	12	91% 41%	4% mesh exposure 0 reoperations POP Baseline dyspareunia resolved 20% Denovo dyspareunia 15% rectocele 10% Denovo dyspareunia 9% 5% reoperations POP, denovo rectocele 10% Baseline dyspareunia resolved 80%
El-Nazier[106]	2012	AC Self-styled polypropylene Gynecare Ethicon	20 21	12	70% 95%	No difference between groups operating time, blood loss, in-patient time 5% mesh erosion
Menefee[107]	2011	AC Self-styled Polypropylene mesh	32 36	24	87% 96%	No reoperation prolapse either group 14% Mesh erosion
Turgal[108]	2013	AC Polypropylene mesh kit Parieten Sofradim	20 20	12	75% 95%	Denovo SUI 5% each group Mesh erosion 15%
Delroy[109]	2013	AC Polypropylene mesh kit Nazca Promedon	39 40	12	56% 82%	5% Mesh exposure
De Tayrac[110]	2013	AC Polypropylene mesh kit Ugtex, Sofradim	82 80	12	64% 89%	2.8% reoperation prolapse 9.5% Mesh erosion, 1 patient re-operated dyspareunia
Tamanini[111]	2014	AC Polypropylene mesh kit Nazca Promedon	55 45	24	64% 76%	No reoperation prolapse either group 16.2% Reoperation rate in mesh group
Gupta[112]	2014	AC Self-Styled Polypropylene Mesh (vypro JnJ)	54 52	12	100% 100%	Optimal or satisfactory outcome 100% in both groups. Operating time and blood loss greater in the mesh group High rate of blood transfusion in both groups

Adapted from Incontinence ICI 2017, 6th Edition

Vaginal mesh for prolapse: a randomized controlled trial

	Mesh N=32	No Mesh N=33
Anatomic Failure >POPQ stage I	59% 19/32	75% 21/33
Subjective cure (PGI-I, PGI-S PFDI-20, PFIQ-7)	No Difference	
Re-operation	2 for Prolapse 3 for Mesh	none

Trial recruitment was stopped early when values exceeded predetermined erosion rate

Iglesia CB Obstet Gynecol 2010; 116:293

Prospective Randomized Clinical Trial

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Anterior Colporrhaphy versus Transvaginal Mesh for Pelvic-Organ Prolapse

Daniel Altman, M.D., Ph.D., Tapio Väyrynen, M.D., Marie Ellström Engh, M.D., Ph.D., Susanne Axelsen, M.D., Ph.D., and Christian Falconer, M.D., Ph.D., for the Nordic Transvaginal Mesh Group*

- 389 subjects with 95% 12 months f/u
- Anatomic Success: POPQ </= stage I
  - 80% in Mesh 47% in Native tissue

CONCLUSIONS

As compared with anterior colporrhaphy, use of a standardized, trocar-guided mesh kit for cystocele repair resulted in higher short-term rates of successful treatment but also in higher rates of surgical complications and postoperative adverse events.

- Re-operation rate
  - 3% with Mesh 0.5% with native tissue

Conclusions

As compared with anterior colporrhaphy, use of a standardized, trocar-guided mesh kit for cystocele repair resulted in higher short-term rates of successful treatment but also in **higher rates of surgical complications and postoperative adverse events.**

Altman et al NEJM 2011: 364: 1826

Cochrane review - mesh/ native tissue

- The risk-benefit profile means that transvaginal mesh has limited utility in primary surgery.
- It is possible that in women with higher risk of recurrence the benefits may outweigh the risks, but there is currently no evidence to support this position.

Maher C, Feiner B, Baessler K, Christmann-Schmid C, Haya N, Marjoribanks J.

Cochrane Database Syst Rev. 2016 Feb 9;2:CD012079. doi: 10.1002/14651858.CD012079. Review

THE LANCET

Mesh, graft, or standard repair for women having primary transvaginal anterior or posterior compartment prolapse surgery: two parallel-group, multicentre, randomised, controlled trials (PROSPECT)

*Cathryn MA Glazener, Suzanne Breeman, Andrew Elders, Christine Hemming, Kevin G Cooper, Robert M Freeman, Anthony RB Smith, Fiona Reid, Suzanne Hagen, Isobel Montgomery, Mary Kilonzo, Dwayne Boyers, Alison McDonald, Gladys McPherson, Graeme MacLennan, John Norrie (for the PROSPECT study group)**

- 2 groups: synthetic mesh inlays or biological grafts against standard repair
- 35 centres and 65 surgeons in UK
- 1348 patients
- 2 years follow up

Augmentation of a vaginal repair with mesh or graft material **did not improve women's outcomes** in terms of effectiveness, quality of life, adverse effects, or any other outcome in the short term, **but more** than one in ten women had a mesh **complication**.

Mesh, graft, or standard repair for women having primary transvaginal anterior or posterior compartment prolapse surgery: two parallel-group, multicentre, randomised, controlled trials (PROSPECT)

The Lancet 2017

*Cathryn MA Glazener, Suzanne Breeman, Andrew Elders, Christine Hemming, Kevin G Cooper, Robert M Freeman, Anthony RB Smith, Fiona Reid, Suzanne Hagen, Isobel Montgomery, Mary Kilonzo, Dwayne Boyers, Alison McDonald, Gladys McPherson, Graeme MacLennan, John Norrie (for the PROSPECT study group)**

	Mesh trial: standard repair *vs* synthetic mesh augmented repair				Graft trial: standard repair *vs* biological graft augmented repair			
	Standard repair	Synthetic mesh	Estimate of treatment effect size	p value	Standard repair	Biological graft	Estimate of treatment effect size	p value
6-month outcomes	N=398	N=381	..	..	N=338	N=335	..	..
POP-SS	4·7 (5·4); 398	5·3 (5·1); 380	0·57 (−0·12 to 1·26)	0·10	5·0 (5·5); 338	4·9 (5·5); 335	−0·44 (−1·23 to 0·35)	0·28
Prolapse-related QoL score†	2·0 (2·8); 390	2·2 (2·7); 374	0·22 (−0·16 to 0·60)	0·26	2·0 (2·9); 332	2·0 (2·7); 330	−0·17 (−0·58 to 0·25)	0·43
Symptomatic prolapse*	79% (314/398)	86% (325/380)	1·07 (1 to 1·14)	0·04	81% (274/338)	81% (271/335)	1·00 (0·93 to 1·08)	0·96
Women with any report of SCD	31% (123/398)	33% (125/380)	1·09 (0·90 to 1·34)	0·38	30% (101/338)	34% (113/335)	1·11 (0·88 to 1·39)	0·38
EQ-5D-3L score	0·82 (0·26); 383	0·83 (0·22); 372	0·01 (−0·02 to 0·04)	0·40	0·82 (0·27); 326	0·82 (0·25); 318	0·01 (−0·02 to 0·05)	0·50
1-year outcomes	N=395	N=389	..	..	N=342	N=337	..	..
POP-SS	5·4 (5·5); 395	5·5 (5·1); 389	0·00 (−0·70 to 0·71)	0·99	5·5 (5·6); 342	5·6 (5·6); 337	−0·15 (−0·93 to 0·63)	0·71
Prolapse-related QoL score†	2·0 (2·7); 389	2·2 (2·7); 380	0·13 (−0·25 to 0·51)	0·50	2·2 (2·8); 335	2·4 (2·9); 330	0·13 (−0·30 to 0·56)	0·54
Symptomatic prolapse*	83% (328/395)	85% (329/389)	1·01 (0·95 to 1·08)	0·64	[illegible]	[illegible]	0·99 (0·93 to 1·06)	0·85
Women with any report of SCD	36% (143/395)	35% (138/389)	0·98 (0·82 to 1·18)	0·85	34% (117/342)	42% (140/337)	1·18 (0·97 to 1·43)	0·10
Severe urinary incontinence‡	6% (21/361)	8% (29/354)	1·34 (0·79 to 2·26)	0·27	8% (26/315)	5% (17/313)	0·61 (0·33 to 1·12)	0·11
Faecal incontinence (any)§	28% (102/365)	25% (91/358)	0·92 (0·74 to 1·13)	0·41	27% (84/316)	25% (77/314)	0·92 (0·72 to 1·17)	0·50
ICI Vaginal Symptoms Score	7·2 (7·2); 338	7·5 (8·1); 327	0·52 (−0·64 to 1·68)	0·38	7·1 (6·9); 294	9·0 (9·1); 294	1·31 (0·04 to 2·59)	0·04
Severe dyspareunia¶	4% (8/186)	5% (9/173)	1·73 (0·52 to 5·78)	0·37	6% (9/149)	5% (8/165)	1·17 (0·43 to 3·23)	0·76
EQ-5D-3L score	0·83 (0·25); 385	0·83 (0·22); 384	0·01 (−0·02 to 0·04)	0·65	0·81 (0·27); 335	0·82 (0·25); 333	0·02 (−0·01 to 0·06)	0·21
2-year outcomes	N=348	N=343	..	..	N=299	N=300	..	..
POP-SS	4·9 (5·1); 347	5·3 (5·1); 342	0·32 (−0·39 to 1·03)	0·37	4·9 (5·1); 298	5·5 (5·7); 299	0·32 (−0·48 to 1·12)	0·43
Prolapse-related QoL score†	1·9 (2·5); 335	2·2 (2·6); 329	0·15 (−0·23 to 0·54)	0·44	2·0 (2·5); 290	2·2 (2·8); 291	0·10 (−0·33 to 0·52)	0·66
Symptomatic prolapse*	82% (283/347)	85% (291/342)	1·04 (0·97 to 1·11)	0·30	81% (242/298)	82% (245/299)	0·99 (0·92 to 1·07)	0·85
Women with any report of SCD	31% (106/347)	34% (116/342)	1·06 (0·85 to 1·32)	0·59	31% (91/298)	40% (120/299)	1·26 (1·01 to 1·58)	0·04
Severe urinary incontinence‡	6% (19/343)	6% (21/334)	1·01 (0·51 to 1·99)	0·97	7% (21/294)	7% (20/297)	0·80 (0·44 to 1·46)	0·47
Faecal incontinence (any)§	26% (89/343)	27% (92/338)	1·13 (0·92 to 1·41)	0·25	27% (81/295)	26% (77/298)	0·95 (0·75 to 1·21)	0·69
ICI Vaginal Symptoms Score	7·0 (7·3); 313	7·3 (7·8); 311	−0·18 (−1·34 to 0·98)	0·76	6·8 (6·8); 271	8·1 (8·8); 278	0·36 (−0·95 to 1·67)	0·59
Severe dyspareunia¶	5% (9/166)	3% (4/145)	0·49 (0·15 to 1·55)	0·22	4% (5/125)	4% (6/154)	0·93 (0·29 to 2·99)	0·90
EQ-5D-3L score	0·81 (0·28); 340	0·83 (0·22); 334	0·02 (−0·02 to 0·06)	0·26	0·81 (0·28); 291	0·82 (0·27); 294	0·03 (−0·01 to 0·07)	0·17

No difference in efficacy

	Standard repair	Synthetic mesh	Estimate of treatment effect size	p value	Standard repair	Biological graft	Estimate of treatment effect size	p value
6-month outcomes	N=398	N=381	..	..	N=338	N=335	..	..
Number readmitted (0–6 months)*	3% (11/398)	3% (12/381)	1·15 (0·51 to 2·57)	0·74	3% (9/338)	4% (14/335)	1·54 (0·68 to 3·51)	0·30
1-year outcomes	N=395	N=389			N=342	N=337		
Number readmitted (6–12 months)*	1% (4/395)	1% (5/389)	1·32 (0·36 to 4·81)	0·68	1% (4/342)	2% (6/337)	1·67 (0·48 to 5·79)	0·42
New prolapse operation	2% (6/395)	3% (12/389)	1·99 (0·76 to 5·24)	0·16	2% (7/342)	3% (10/337)	1·44 (0·56 to 3·73)	0·45
Same compartment	<1% (3/395)	2% (8/389)	2·55 (0·68 to 9·53)	0·16	1% (5/342)	1% (5/337)	0·98 (0·29 to 3·34)	0·98
Different compartment	<1% (3/395)	1% (4/389)	1·35 (0·31 to 5·96)	0·69	<1% (2/342)	1% (5/337)	2·50 (0·49 to 12·74)	0·27
New continence operation	1% (5/395)	<1% (2/389)	0·40 (0·08 to 2·04)	0·27	<1% (2/342)	2% (7/337)	3·49 (0·73 to 16·66)	0·12
Adverse effects in the first year								
Any serious adverse effects† (excluding mesh complications)	7% (31/430)	8% (34/435)	1·08 (0·68 to 1·72)	0·73	6% (23/367)	10% (36/368)	1·57 (0·95 to 2·59)	0·08
Any mesh complications‡	<1% (2/430)	7% (32/435)	..	..	<1% (2/367)	<1% (2/368)	..	..
Surgical removal§	<1% (2/430)	5% (23/435)	..	..	<1% (2/367)	<1% (2/368)	..	..
Conservative treatment	(0/430)	2% (8/435)	..	..	(0/367)	(0/368)	..	..
No treatment	(0/430)	<1% (1/435)	..	..	(0/367)	<1% (1/368)	..	..
De novo mesh procedure¶	<1% (1/430)	6·2% (27/435)	..	..	(0/367)	(0/368)	..	..
Concomitant mesh procedure‖	<1% (1/430)	1% (5/435)	..	..	<1% (2/367)	<1% (2/368)	..	..
2-year outcomes	N=348	N=343	..	..	N=299	N=300	..	..
Number readmitted (12–24 months)*	<1% (3/348)	(0/343)	..	..	<1% (2/299)	1% (4/300)	1·95 (0·36 to 10·56)	0·44
New prolapse operation	5% (16/348)	4% (15/343)	0·94 (0·47 to 1·88)	0·87	5% (15/299)	5% (15/300)	0·99 (0·49 to 1·98)	0·98
Same compartment	3% (9/348)	2% (7/343)	0·79 (0·30 to 2·11)	0·64	2% (7/299)	3% (8/300)	1·13 (0·41 to 3·06)	0·82
Different compartment	2% (7/348)	2% (8/343)	1·14 (0·42 to 3·10)	0·80	3% (8/299)	2% (7/300)	0·86 (0·32 to 2·33)	0·76
New continence operation	1% (4/348)	1% (5/343)	1·28 (0·35 to 4·73)	0·71	2% (7/299)	1% (4/300)	0·56 (0·17 to 1·90)	0·35
Adverse effects in second year								
Any serious adverse effects† (excluding mesh complications)	1% (6/430)	<1% (4/435)	0·66 (0·19 to 2·30)	0·51	1% (4/367)	1 % (5/368)	1·25 (0·34 to 4·60)	0·74
Any mesh complications	<1% (1/430)	6% (25/435)	..	..	<1% (1/367)	<1% (1/368)	..	..
Surgical removal**	(0/430)	4% (17/435)	..	..	(0/367)	(0/368)	..	..
Conservative	<1% (1/430)	<1% (4/435)	..	..	<1% (1/367)	(0/368)	..	..
No treatment	(0/430)	<1% (4/435)	..	..	(0/367)	<1% (1/368)	..	..
De novo mesh procedure¶	(0/430)	5·3% (23/435)	..	..	(0/367)	(0/368)	..	..
Concomitant mesh procedure‖	<1% (1/430)	<1% (2/435)	..	..	(0/367)	<1% (1/368)	..	..

Higher rate of complications with mesh

Augmentation of a vaginal repair with mesh or graft material did not improve women's outcomes in terms of eff ectiveness, quality of life, adverse eff ects, or any other outcome in the short term, but more than one in ten women had a mesh complication. Therefore, follow-up is vital to identify any longer-term potential benefi ts and serious adverse eff ects of mesh or graft reinforcement in vaginal prolapse surgery

U.S. Food and Drug Administration

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence

Issued: October 20, 2008

Dear Healthcare Practitioner:

This is to alert you to complications associated with transvaginal placement of surgical mesh to treat Pelvic Organ Prolapse (POP) and Stress Urinary Incontinence (SUI). **Although rare, these complications can have serious consequences**. Following is information regarding the adverse events that have been reported to the FDA and recommendations to reduce the risks.

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

- From 2008 – 2010, frequent complications POP meshes repair include erosion, pain, infection, bleeding, dyspareunia, organ perforation, urinary problems, recurrent prolapse, neuro-muscular problems, vaginal scarring /shrinkage, and emotional problems, many requiring additional intervention and hospitalization.

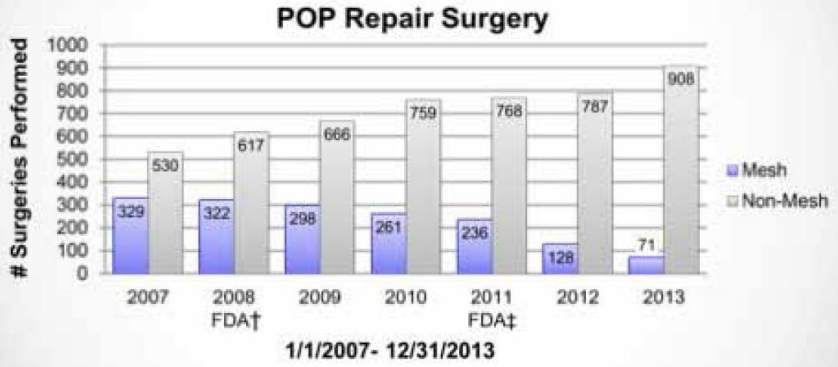
- By July 2011, 4000 complaints of injury, death or malfunction associated with TVM within the 5 previous years were reported.

- 2016, all TVM became class III (need of post-market surveillance-522) (Some manufacturers withdraw their meshes from the USA market)

- 2015, 73,000 women had filed lawsuits against mesh manufacturers after suffering serious damage from their products
- January 2016 : Reclassification of surgical mesh and PMA (pre-market approval)

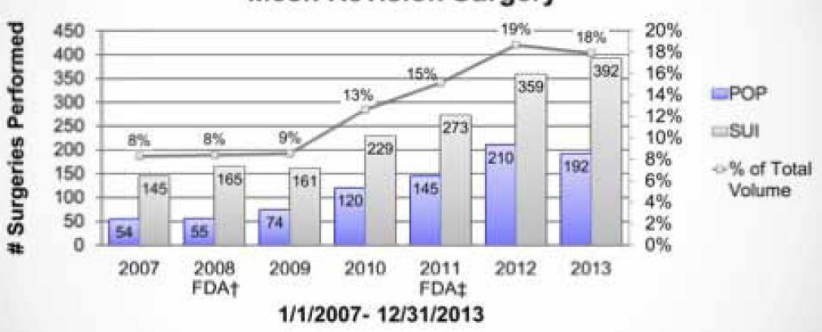
http://www.fda.gov

CHANGING PRACTICE PATTERNS IN VAGINAL MESH SURGERY (Multi-institutional)
Results



POP repair using mesh has drastically decreased.

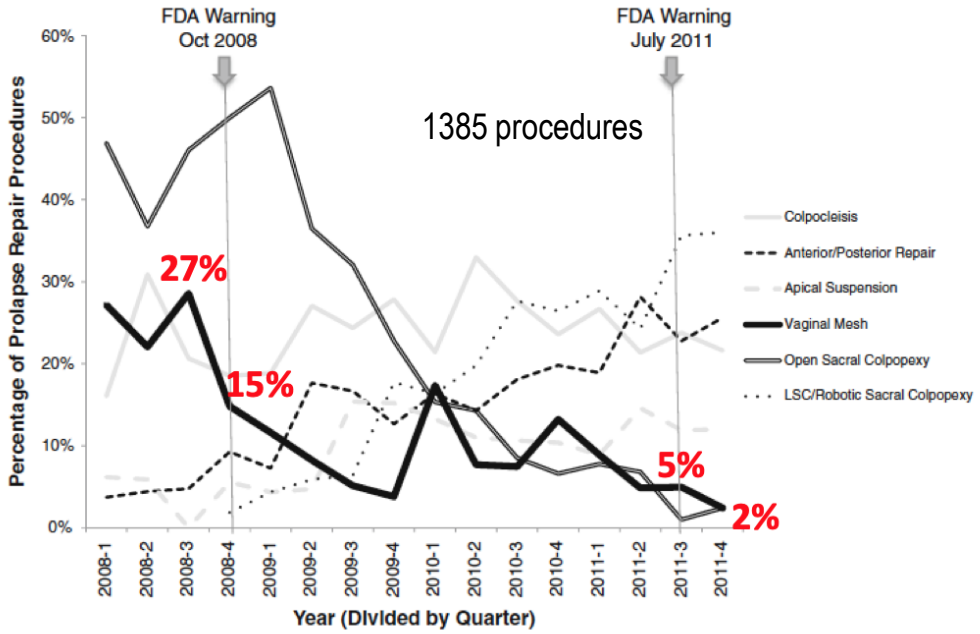
CHANGING PRACTICE PATTERNS IN VAGINAL MESH SURGERY (Multi-institutional)
Results



Mesh revision surgery as a percentage of total case volume has steadily increased from 8% in 2007 to 18% in 2013.

Rovner, AUA News, April 2019

Trends in Prolapse Repairs Over Time

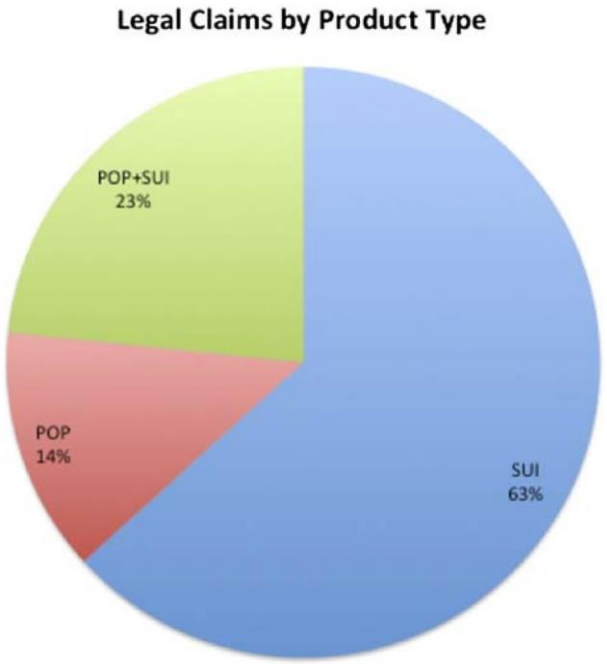


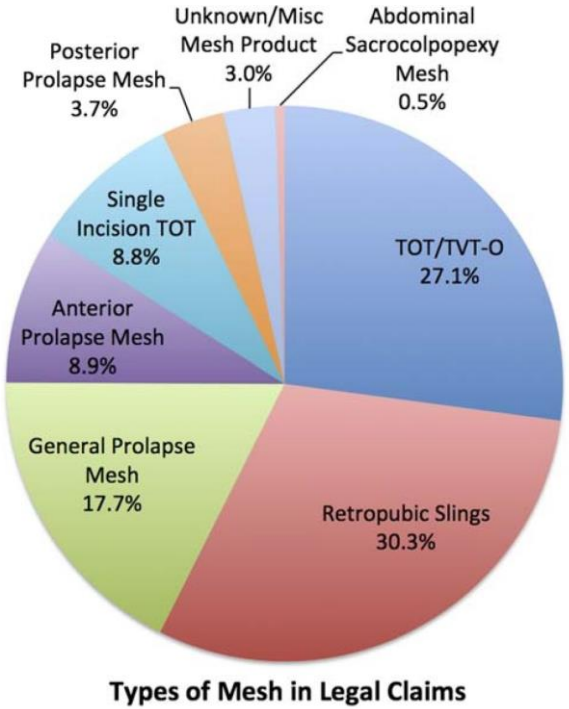
Skozylas LC, IUJ 2014

The Truth Behind Transvaginal Mesh Litigation: Devices, Timelines, and Provider Characteristics

Colby P. Souders, MD, Karyn S. Eilber, MD,† Lynn McClelland, JD, MPH,‡ Lauren N. Wood, MD,* Alexander R. Souders, JD,§ Vicki Steiner, JD,‡ and Jennifer Tash Anger, MD, MPH‖*

Female Pelvic Medicine & Reconstructive Surgery • Volume 24, Number 1, January/February 2018





Most legal claims involved slings for SUI and began after the 2011 Food and Drug Administration communication about mesh for POP. The rise in lawsuits does not reflect the acceptably low complication rates for slings for SUI reported in the literature

NEWS

Woman is jailed after exaggerating injuries from vaginal mesh operation

Clare Dyer

The BMJ

A woman who tried to defraud the NHS of £2.3m (€2.7m; $3m) by making an exaggerated clinical negligence claim over an unnecessary vaginal mesh operation in 2010 has been given a five month jail sentence.

Lesley Elder, 50, claimed she was in constant pain and could no longer work, walk unaided, or go on holiday, but was caught out by a Facebook photo of her in 2012 at her daughter's hen party in Ibiza.

Investigators acting on behalf of the NHS put Elder under surveillance in 2016 and filmed her walking unaided, lifting her grandson, and visiting the shops and supermarket.

George Eliot Hospital NHS Trust in Nuneaton admitted liability in putting her through unnecessary surgery. But in 2017 a county court awarded her £120 012, the judge noting that but for the surveillance "a terrible injustice would have been done to the National Health Service."

Following the trial, the trust took committal proceedings against Elder at the High Court, asking for her to be jailed for contempt of court over her lies during the case.

Jailing her, Judge Karen Walden-Smith said Elder's conduct included "extensive and widespread exaggeration and lies."

She added, "It is quite plain in this case that the custody threshold is crossed. This was deliberate and persistent making of false statements for the purpose of falsely recovering significant monies from a publicly funded body."

Walden-Smith accepted that Elder, who had worked as a support worker for disabled children, had suffered a genuine injury and was of previous good character. But she added, "Taking into account all the matters before me and given the great seriousness of this contempt, I have come to the conclusion that the appropriate punishment in this case is one of immediate custody."

The sentence was passed in Elder's absence. The hearing was delayed after she apparently swallowed a handful of tranquillisers in court. She is expected to serve half of the five month sentence and the remainder on licence.

The case is the second in which the NHS has taken action over a fraudulent clinical negligence claim. Last year, Sundip Singh Atwal, a taxi driver, was jailed for three months for claiming £837 000 for injuries worth no more than £30 000.[1]

"Fraudulent claims for compensation against the NHS take money away from patient care," said Helen Vernon, chief executive of NHS Resolution. "We are pleased that the seriousness of this case has been recognised by the courts. NHS Resolution is committed to compensating genuine claimants fairly but this case highlights the likely consequences for anyone who tries to pursue a dishonest or exaggerated claim."

1 Dyer C. Patient found in contempt of court for trying to claim £837 000 from hospital trust. *BMJ* 2018;361:k1913. 10.1136/bmj.k1913 29712640

NHS Mesh working group

- For many women suffering the distressing effects of SUI and POP, surgical procedures using vaginal mesh devices have provided an **effective form of treatment which can be far less invasive than alternative surgical procedures.**

- However, the **safety and efficacy of surgery for SUI and POP using mesh devices has been questioned by a community of patients and clinicians**.

- NHS England set up the Mesh Working Group to address these concerns.

- The Working Group published its Interim Report in 2015 which sets out recommendations to optimise care for women undergoing treatment for SUI and POP.

- Those recommendations were implemented working alongside National Institute for Health and Care Excellence (**NICE**), British Association of Urological Surgeons (**BAUS**), British Society of Urogynaecology (**BSUG**), Royal College of Obstetricians and Gynaecologists (**RCOG**), Medicines and Healthcare products Regulatory Agency (**MHRA**), Department of Health **(DH**) and of course our patient members.

2017

Mesh Oversight Group Report

- Improvements needed in: patient information
  -consent
  -shared decision-making
  -procedure recording
  -complication reporting

- All appropriate treatments (nonsurgical, mesh and non-mesh) should be offered to patients in fully informed consultations.

- Care should be delivered by a multidisciplinary team of appropriately trained and experienced specialists.

- All cases should be registered on an appropriate database such as those provided by BSUG and BAUS

- Minimal number and audit
  No n. for POP but for SUI surgery at least 20/year. Surgeons undertaking fewer than 5 cases of any procedure annually should do so only with the support of their clinical governance committee.

The Scottish Government
Riaghaltas na h-Alba

FDA News Release

FDA takes action to protect women's health, orders manufacturers of surgical mesh intended for transvaginal repair of pelvic organ prolapse to stop selling all devices

For Immediate Release

April 16, 2019

The European Commission, requested the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) to assess the health risks of meshes used in urogynaecological surgery. EAU-EUGA consensus follows and supports the deliberations of SCENIHR panel

EUROPEAN UROLOGY 72 (2017) 424–431

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

European Association of Urology

Review – Incontinence

Consensus Statement of the European Urology Association and the European Urogynaecological Association on the Use of Implanted Materials for Treating Pelvic Organ Prolapse and Stress Urinary Incontinence

Christopher R. Chapple [a,], Francisco Cruz [b,c], Xavier Deffieux [d], Alfredo L. Milani [e], Salvador Arlandis [f], Walter Artibani [g], Ricarda M. Bauer [h], Fiona Burkhard [i], Linda Cardozo [j], David Castro-Diaz [k], Jean Nicolas Cornu [l], Jan Deprest [m], Alfons Gunnemann [n], Maria Gyhagen [o], John Heesakkers [p], Heinz Koelbl [q], Sheila MacNeil [r], Gert Naumann [s], Jan-Paul W.R. Roovers [t], Stefano Salvatore [u], Karl-Dietrich Sievert [v], Tufan Tarcan [w], Frank Van der Aa [x], Francesco Montorsi [y], Manfred Wirth [z], Mohamed Abdel-Fattah [aa]*

European Commission

EAU/EUGA Recommendations :

Synthetic sling tapes have well-established success rates and safety profile

It is Important to differentiate between the use of synthetic tapes for the treatment of SUI and large surface areas of mesh for treating POP

- **Tape-related morbidity is un-common but may occur any time during or after implantation**
- **Existing data do not allow reliable quantification of tape specific long term risks.**

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Consensus view POP

- **Use of vaginal mesh for POP should be considered only in complex cases when other surgical procedures have already failed or are expected to fail or in the context of ethics committee approved clinical research**
- **Its use should also be restricted to expert individuals working in specialised departments**
- **Whilst the risk associated with the trans-abdominal insertion of mesh for POP is considered more acceptable, its use should also be restricted to specialist practice**

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Consensus view SUI

- Synthetic tapes for SUI have well-established success rates and safety
- Efficacy is higher than colposuspension and comparable to autologous slings but with lesser morbidity compared to colposuspension
- Mesh-related morbidity is un-common but may occur either at the time of implantation (e.g., bladder perforation or vascular/ bowel injury) or subsequently (e.g., mesh exposure, pain or erosion into the urinary tract).
- Existing data do not allow reliable quantification of mesh long term risks
- Therapy should only be instituted in accordance with EAU guidelines and with full informed consent of all patients.

Cochrane Library
Cochrane Database of Systematic Reviews

Mid-urethral sling operations for stress urinary incontinence in women (Review)

Ford AA, Rogerson L, Cody JD, Aluko P, Ogah JA *2017*

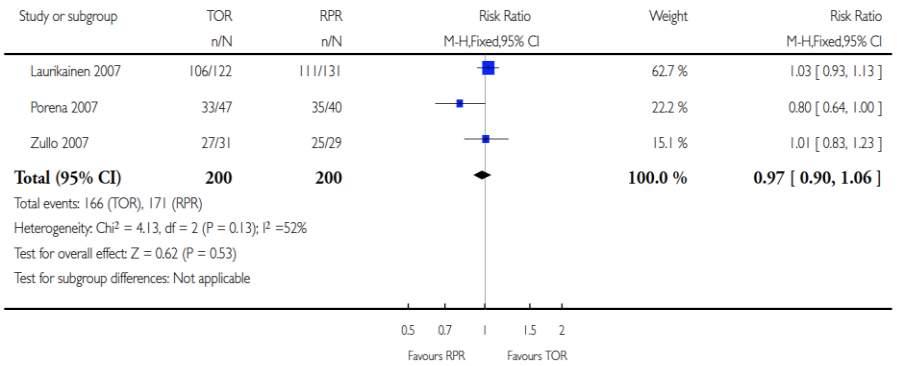
81 trials, 12,113 women

Analysis 1.9. Comparison 1 Transobturator (TOR) versus retropubic route (RPR), Outcome 9 Objective cure (long term, > 5 years).

Review: Mid-urethral sling operations for stress urinary incontinence in women

Comparison: 1 Transobturator (TOR) versus retropubic route (RPR)

Outcome: 9 Objective cure (long term, > 5 years)

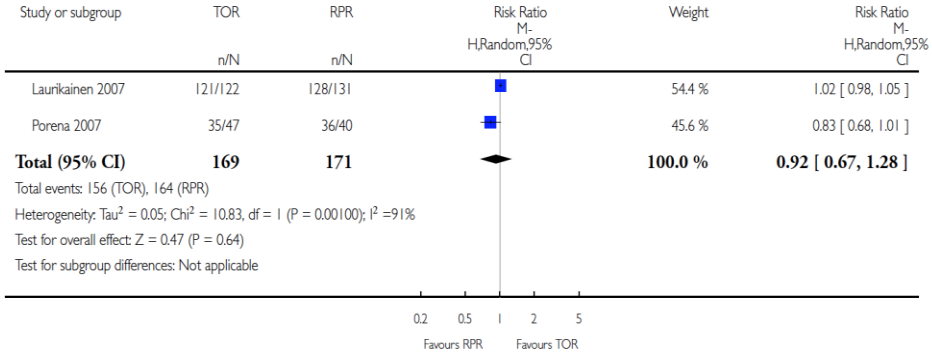


Analysis 1.5. Comparison 1 Transobturator (TOR) versus retropubic route (RPR), Outcome 5 Subjective cure and improvement (long term, > 5 years).

Review: Mid-urethral sling operations for stress urinary incontinence in women

Comparison: 1 Transobturator (TOR) versus retropubic route (RPR)

Outcome: 5 Subjective cure and improvement (long term, > 5 years)



Conclusions

- MUS extensively researched procedure for SUI
- Good safety profile.
- Highly effective in short, medium and long term
- Positive impact on QoL of women with SUI
- TOT >cost-effective compared with RP
- Fewer adverse events with TOT with exception of groin pain
- For TOT no difference between in-out or out-in route
- For RP bottom-top route more effective than top –bottom
- Need for reporting longer-term outcome data from the numerous existing trials.

Assessment of the long-term outcome of TVT procedure for stress urinary incontinence in a female population: results at 17 years' follow-up

Bakas P, 2018

Subjective cure rates at 5, 7, and 17 years' follow-up

	5 years (65/70)	7 years (61/65)	17 years (56/61)	p
Subjectively cured, % (n/N)	84.6 (55/65)	78.7 (48/61)	78.6 (44/56)	0.95*
				0.75**
Subjectively cured considering those patients lost to follow-up as failures, % (n/N)	78 (55/70)	73.8 (48/65)	72.1 (44/61)	0.94*
				0.73**
Subjectively cured considering those patients lost to follow-up that maintain their last outcome, % (n/N)	82.8 (58/70)	76.9 (50/65)	75 (46/61)	0.97*
				0.82**

Objective cure rates at 5, 7, and 17 years' follow-up

	5 years (65/70)	7 years (61/65)	17 years (56/61)	p
Objectively cured (stress test), % (n/N)	83 (54/65)	80.3(49/61)	83.9(47/56)	0.97*
				0.81**
Objectively cured considering those patients lost to follow-up as failures, % (n/N)	77.1(54/70)	75.4(49/65)	77.04 (47/61)	0.99*
				0.86**
Objectively cured considering those patients lost to follow-up that maintain their last outcome, % (n/N)	81.4(57/70)	78.5(51/65)	80.3(49/61)	0.98*
				0.88**

Clavien–Dindo classification of long-term complications up to 17 years' follow-up (N = 56)

Complication	% n	Action
Clavien grade I		
Difficulty emptying the bladder	17.8 (10/56)	Observation
Clavien grade II		
OAB symptoms	30.3 (17/56)	Antimuscarinics/β3 agonists
Recurrent UTI	3.5 (2/36)	Antibiotic therapy ± prophylaxis
Clavien grade IIIa		
Tape exposure	1 (1.7)	Cutting of the projecting edges of tape into the vagina and local estrogens.

The **TVT procedure** for the management of stress urinary incontinence in women **maintains its efficacy in the long term,** having an objective cure rate of 83.9% and a subjective cure rate of 78.6% at 17 years' follow-up, with a **very low complications rate**

Surgical Treatment of Female Stress Urinary Incontinence: AUA/SUFU Guideline

Kathleen C. Kobashi, Michael E. Albo, Roger R. Dmochowski, David A. Ginsberg, Howard B. Goldman, Alexander Gomelsky, Stephen R. Kraus, Jaspreet S. Sandhu, Tracy Shepler, Jonathan R. Treadwell, Sandip Vasavada and Gary E. Lemack

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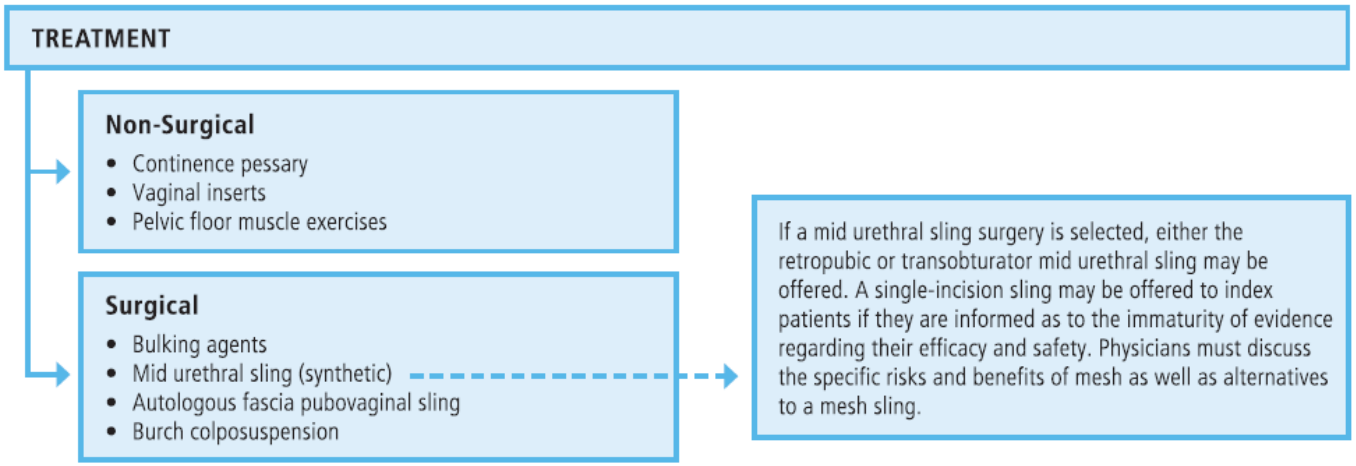
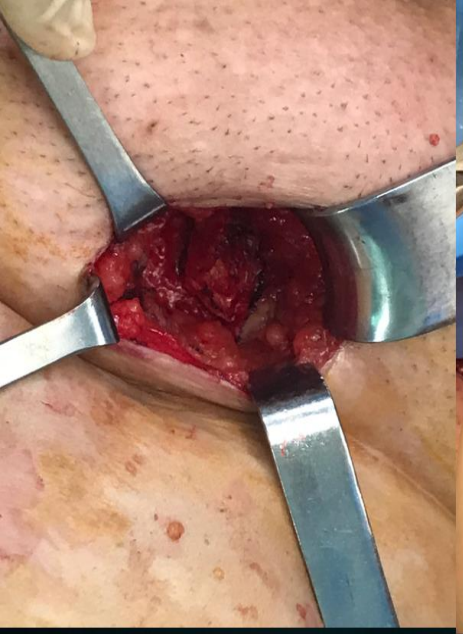
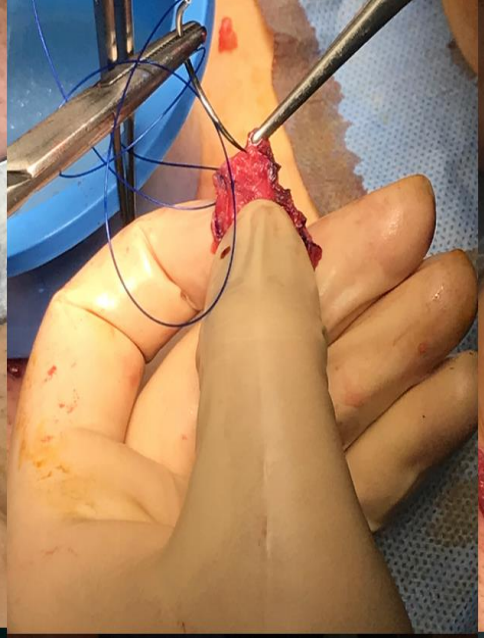
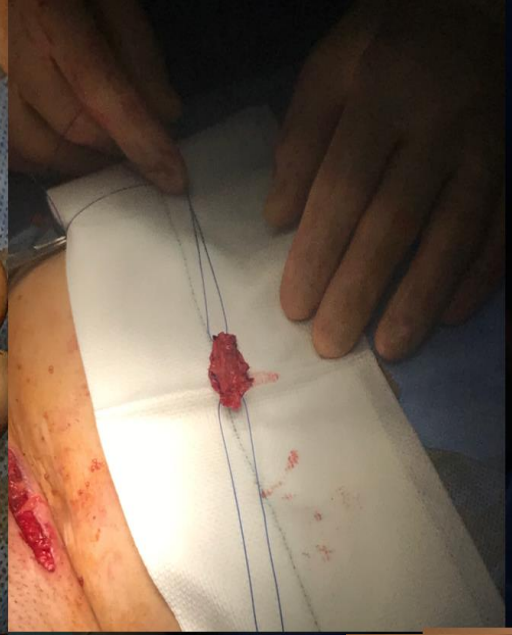


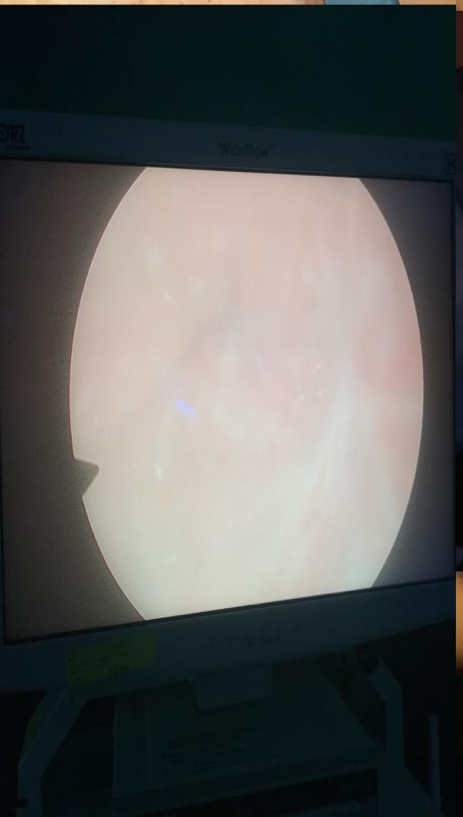
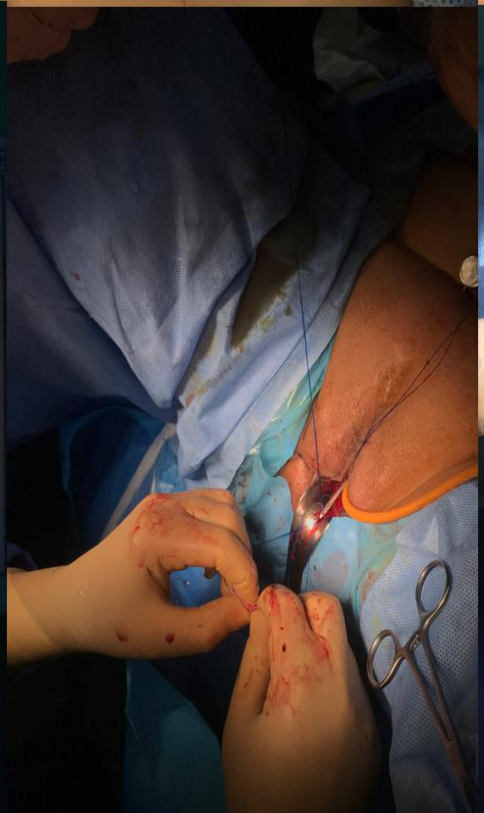
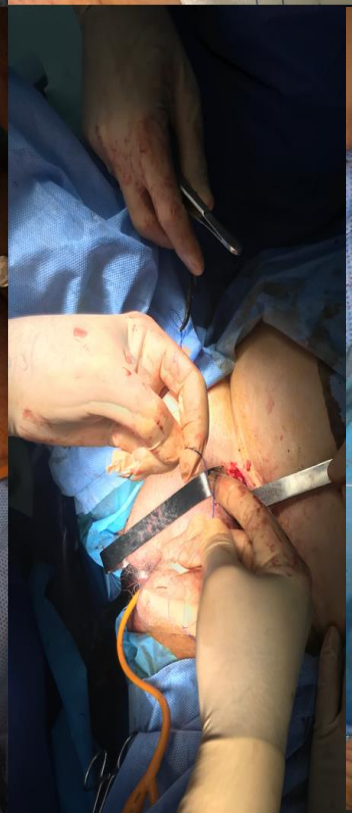
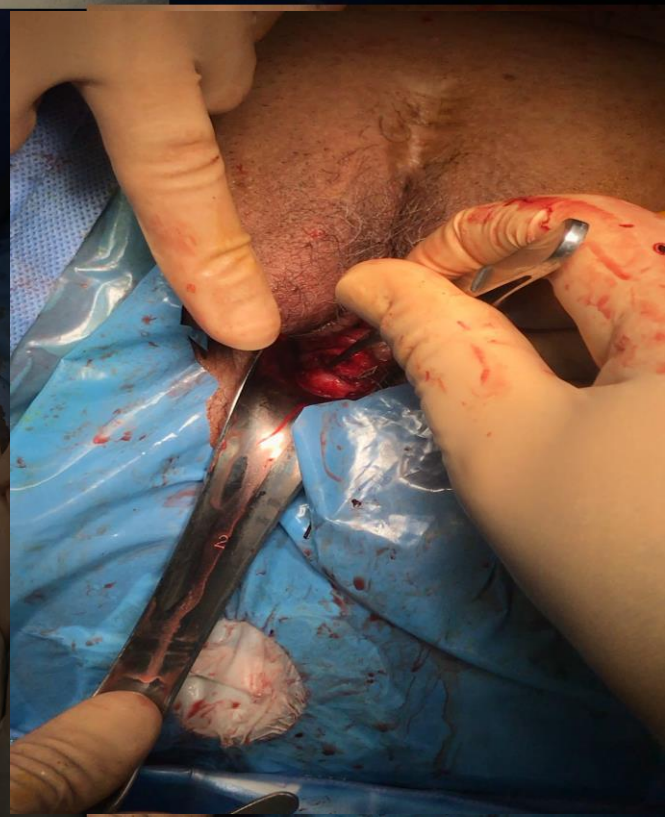
IUGA international urogynecological association

Position Statement on Mid-Urethral Slings for Stress Urinary Incontinence

There is robust evidence to support the use of MUS from over 2,000 publications making this treatment the most extensively reviewed and evaluated procedure for female stress urinary incontinence now in use.

Recommendations (European Association of Urology Guidelines)	Strength rating
Offer MUS, colposuspension or autologous fascial slings to women with uncomplicated SUI	Strong
Inform women who are being offered a single-incision sling that long-term efficacy remains uncertain.	Strong
Inform women of the unique complications associated with each individual procedure	Strong

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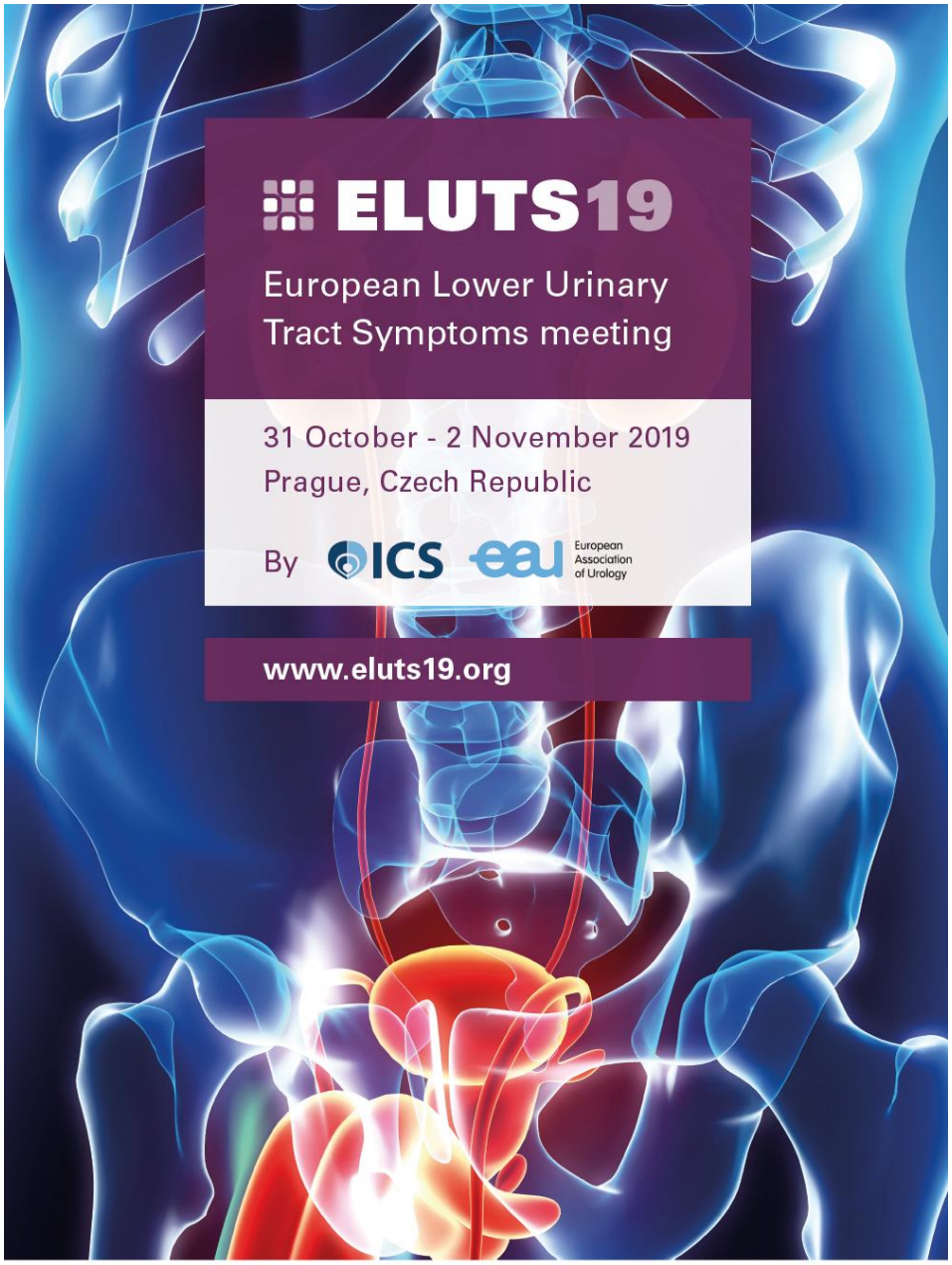
ELUTS19
European Lower Urinary Tract Symptoms meeting
31 October - 2 November 2019
Prague, Czech Republic
By ICS eau European Association of Urology
www.eluts19.org
In collaboration with esffu esgurs esuo esau esu eau European School of Urology