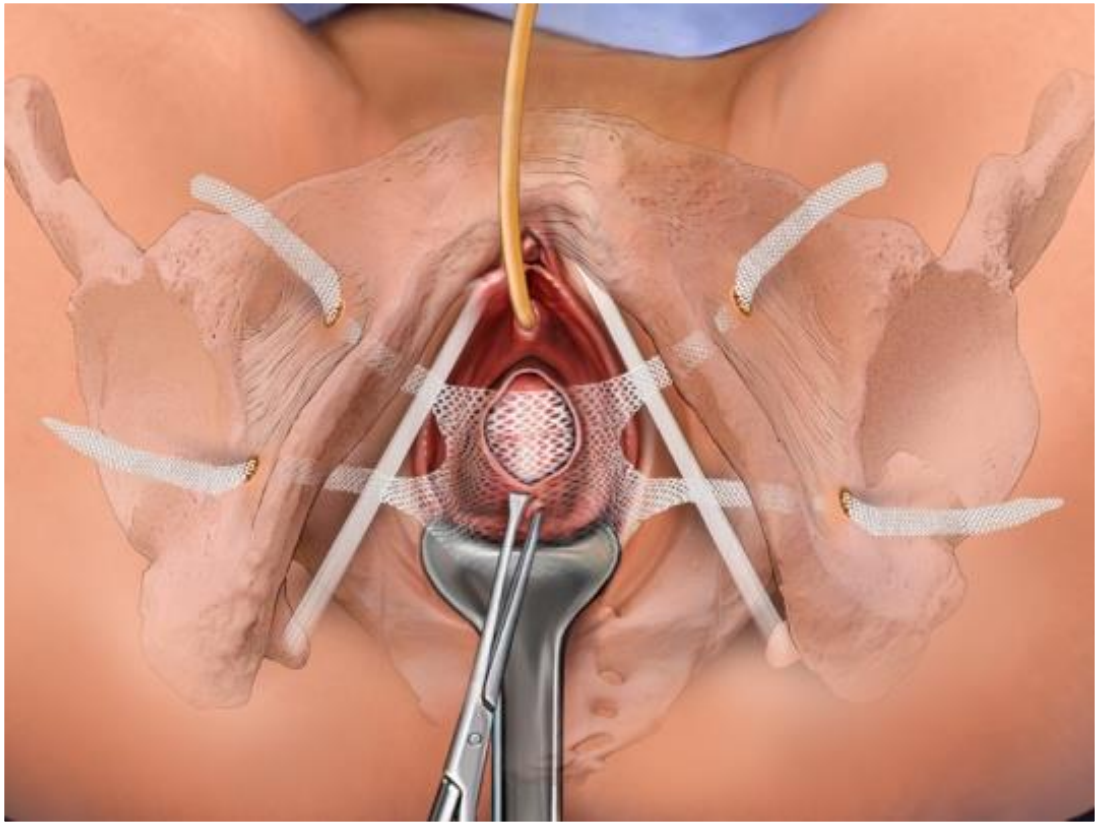
The future of mesh repair of POP after the FDA in the Mediterranean



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Conflict of interest

- Consultant for BOSTON SCIENTIFIC
- Partnership with
  - ETHICON
  - SOFRADIM-COVIDIEN
  - COLOPLAST
  - ASPIDE MEDICAL
  - ASTELLAS
  - SANOFI
  - ROTTAPHARM
  - ALLERGAN

Personal experience

- Use meshes in vaginal surgery since 1999
- Prolene® mesh 1999-2003

de Tayrac R et al., Am J Obstet Gynecol 2002 (Ant repair, 1-year results)
de Tayrac R et al., J Reprod Med 2005 (Ant repair, 2-year results)
de Tayrac R et al., Int Urogynecol J 2006 (Ant repair, 3-year results)
de Tayrac R et al., Int Urogynecol J 2006 (Post repair, 2-year results)
Letouzey V, de Tayrac et al., Eur J Obstet Gynecol 2010 (5-year results)

- Soft-Prolene® 2003-2004

Deffieux X, de Tayrac R et al., Int Urogynecol J 2006

- Collagen-Coated Mesh (Ugytex®-Pelvitex®-Avaulta®) 2003-2007

de Tayrac R et al., Int Urogynecol J 2006 (Animal study)
de Tayrac R et al., Int Urogynecol J 2006 (Multicentre Study, 230 pts)
Mourtialon P, de Tayrac et al., Int Urogynecol J 2012 (Ant repair, 3-year)
Mourtialon P, de Tayrac et al., Int Urogynecol J 2013 (Post repair, 3-year)
de Tayrac R et al, Int Urogynecol J 2013 (RCT)

- Mesh fixed to SS ligaments (Polyform®-Pinnacle®-Uphold®) since 2007

de Tayrac R et al., Int Urogynecol J 2009 (Multicentre study)
Cayrac M et de Tayrac R et al., Int Urogynecol J 2012 (Anatomical study)
de Tayrac R et al., Eur J Obstet Gynecol 2012 (Learning curve)
Rivaux G, de Tayrac R et al., Prog Urol 2012 (Uphold)
Ruzavy Z, de Tayrac R et al., Int Urogynecol J 2013 (voiding function)

- ~ 900 cases (50/y 2003-2007 and 100/y 2008-2014)

10-year risk of reoperation

17% (underestimated),
risk factors not clearly identified…
but abdominal approach is protective (OR 0.37)
and abdominal approach is protective <u>because of mesh</u>

AUGS PAPERS www.AJOG.org

Reoperation 10 years after surgically managed pelvic organ prolapse and urinary incontinence

Mary Anna Denman, MD; W. Thomas Gregory, MD; Sarah H. Boyles, MD, MPH; Virginia Smith, MD; S. Renee Edwards, MD; Amanda L. Clark, MD

OBJECTIVE: This study measured the 10-year risk of reoperation for surgically treated pelvic organ prolapse and urinary incontinence (POPUI) in a community population.

STUDY DESIGN: We conducted a prospective cohort analysis of 374 women who were > 20 years old and who underwent surgery for POPUI in 1995.

RESULTS: The 10-year reoperation rate was 17% by Kaplan Meier analysis. Previous POPUI surgery at the time of index surgery conferred a hazard ratio of 1.9 (95% CI, 1.1-3.2; $P = .018$). The abdominal approach was protective against reoperation compared with the vaginal approach (hazard ratio, 0.37; 95% CI, 0.17-0.83; $P = .02$) With the use of Cox regression, no association was observed for age, vaginal parity, previous hysterectomy, body mass index, prolapse severity, ethnicity, chronic lung disease, smoking, estrogen status, surgical indication, or anatomic compartment.

CONCLUSION: A reoperation rate of 17% is unacceptably high and likely represents an underestimate of the true rate. Most of the factors that influence reoperation have not yet been identified.

Key words: pelvic organ prolapse, surgery, urinary incontinence

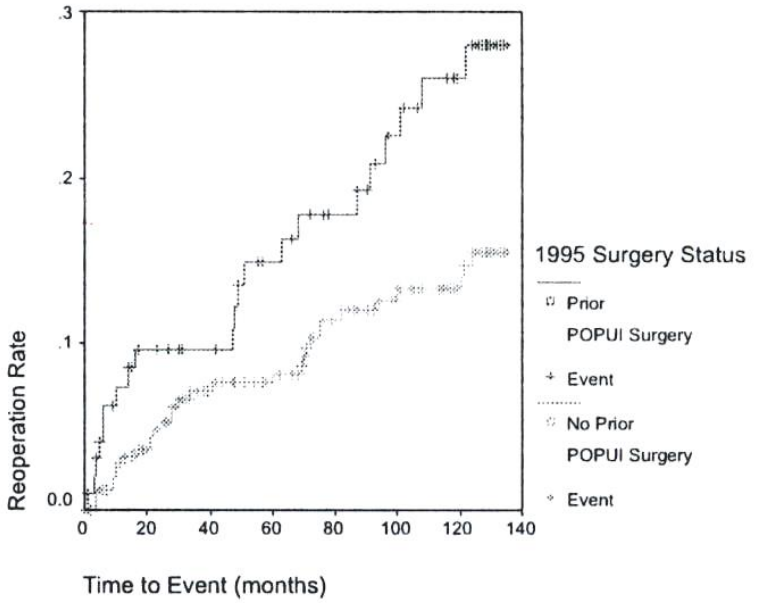
Cite this article as: Denman MA, Gregory WT, Boyles SH, Smith V, Edwards SR, Clark AL. Reoperation 10 years after surgically managed pelvic organ prolapse and urinary incontinence. Am J Obstet Gynecol 2008;198:555.e1-555.e5.

Reoperation risks
increase
in recurrent cases

from 14% to 26%

FIGURE 1

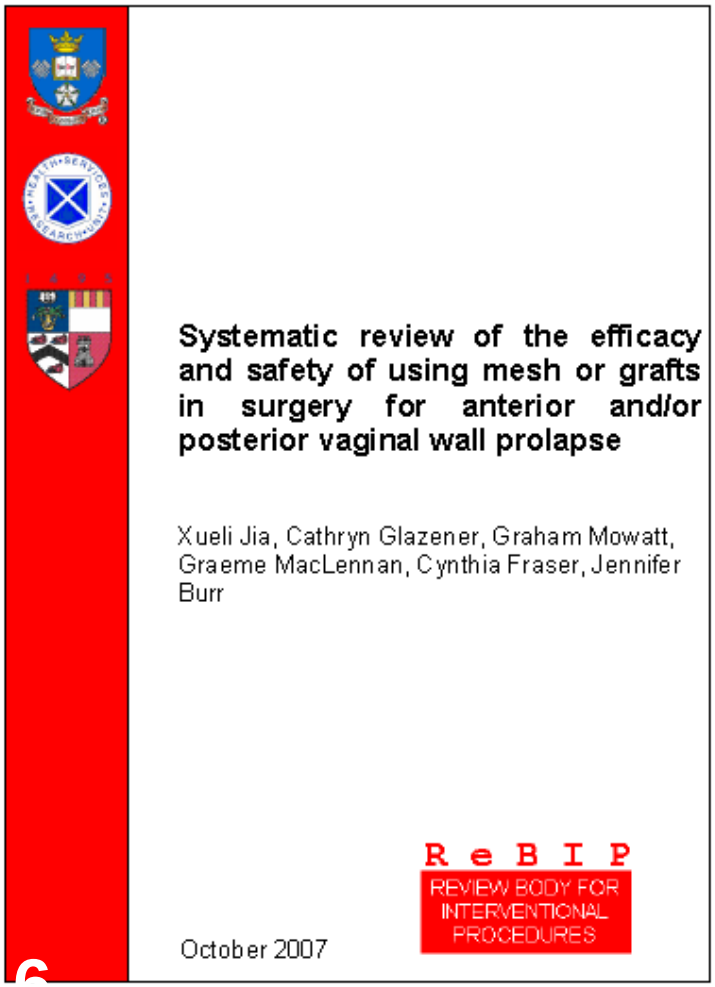
Reoperation risk by surgery status, 1995-2005



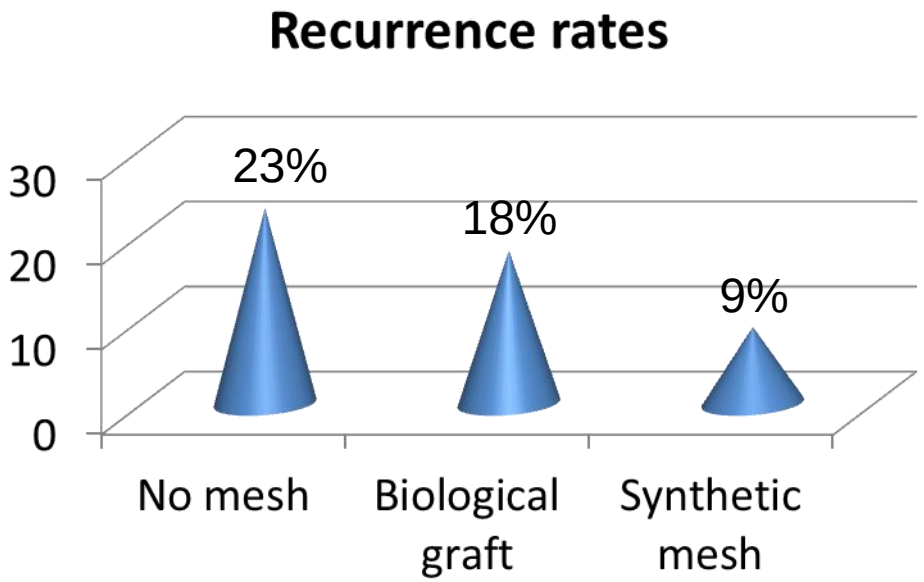
A comparison of reoperation rate for subjects with previous POPUI surgery (26%) with the rate for subjects with no previous surgery (14%) at the time of index surgery. Hazard ratio, 1.9; 95% CI, 1.1-3.2; $P = .02$.

NICE

and Aberdeen University review 2007



49 studies (including 17 RCTs)
4569 patients treated
with/without vaginal mesh/graft

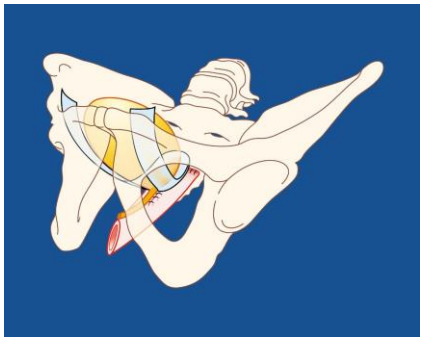


RCTs

Authors	n	Success with mesh	Success with no mesh	p
Hiltunen 2007	215	**61.5**	**93.3**	<.001
N'Guyen 2008	76	**55**	**89**	<.01
Sivaslioglu 2008	90	**72**	**91**	.004
Carey 2009	139	**65.6**	**81**	NS
Altman 2011	389	**34.5***	**60.8***	<.05
de Tayrac 2013	162	**64**	**89**	<.001

HILTUNEN et al., Obstet Gynecol 2007
N'GUYEN et al., Obstet Gynecol 2008
SIVASLIOGLU et al., Int Urogynecol J 2008

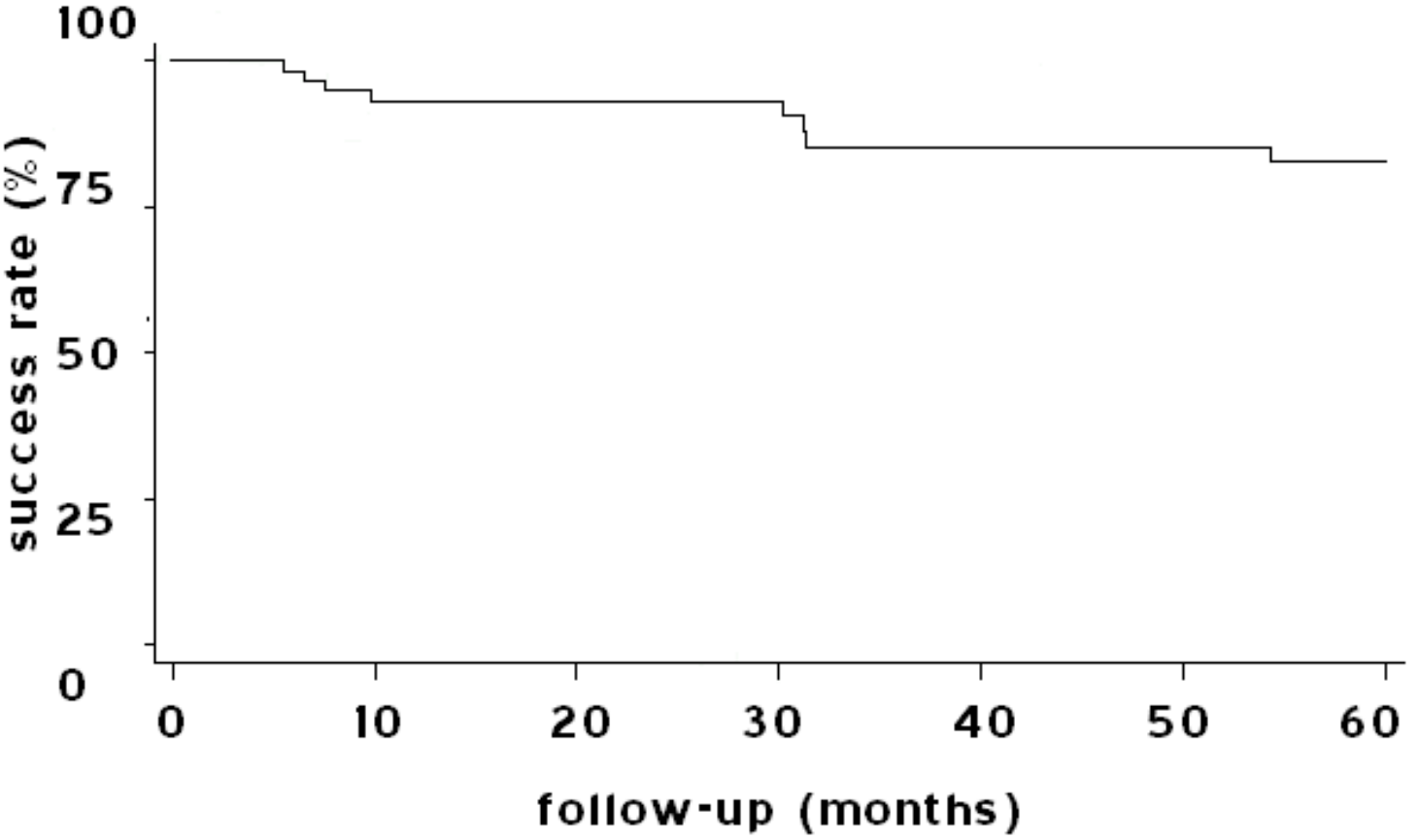
CAREY et al., Br J Obstet Gynecol 2009
ALTMAN et al., NEJM 2011
**Composite criteria (anatomic and functional)*
de TAYRAC et al., Int Urogynecol J 2013



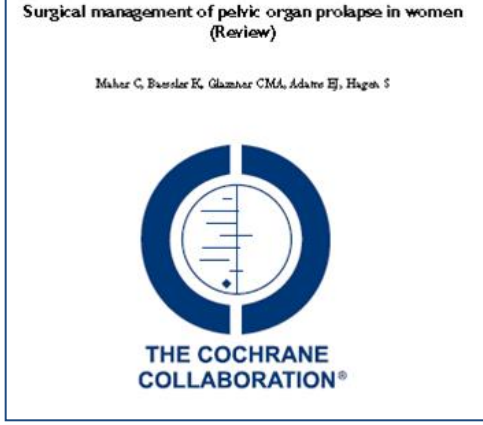
Long-term efficacy ?

5 years success
77.8%
(49/63)

considering the 8 patients lost to follow-up as failure



de TAYRAC et al., *Int Urogynecol J* 2006



Cochrane 2013

Strong evidence of mesh superiority for anterior repair

- ✓ 40 RCTs
- ✓ Increased risk of recurrent cystocele with traditionnal repair compared to trans-obturator mesh

  RR 3.55 (IC95% 2.29-5.51)
- ✓ No significant difference on functional results, because of mesh-related complications (shrinkage, exposure, pain, dyspareunia)
- ✓ No increased risk of re-intervention

Maher C et al., Int Urogynecol J 2013

Our actual indications for synthetic prosthesis

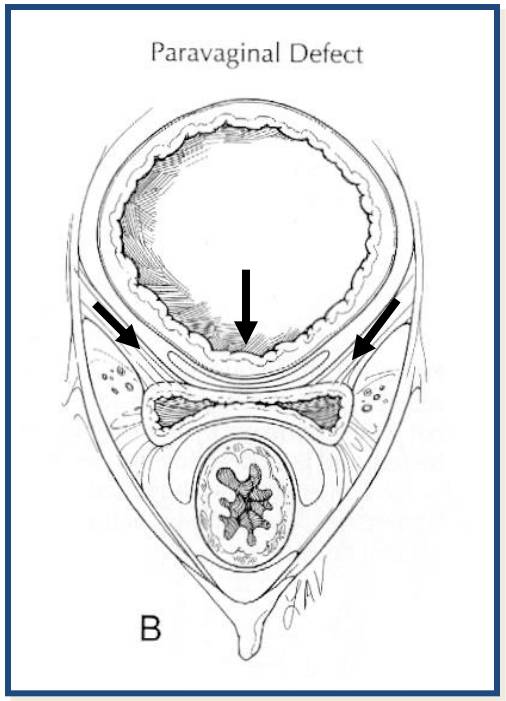
1. Recurence after previous anterior repair

2. Prolapse of stage ≥ 3 (> +1 cm hymen)

   Particularly if both central and lateral defect

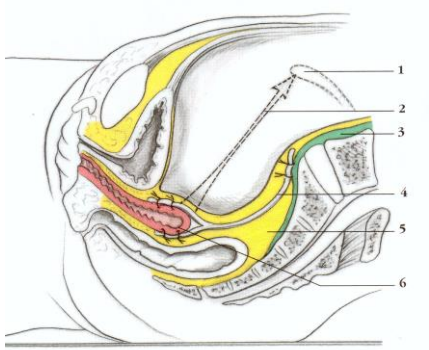
   Particularly in active / obese patient

3. Contra-indication for laparoscopic SCP



< 50-60 y.o.

- Gold standard = Sacrocolpopexy



> 70-80 y.o.

- Decreasing of physical activities
- Acceptance of pessaries
- Efficacy of colpocleisis
- Risk of vaginal erosions increases (vaginal atrophy)

  Multivariate analysis on 138 patients

  with 27 vaginal erosions (20%)

  Patients of > 70 ans

  OR 3,6 [95% CI 1,3-9,7] p=0,01

DEFFIEUX et al., *Int Urogynecol J* 2005

Absolute contra-indications for synthetic mesh

- Previous post-op infection with mesh
- Previous pelvic radiotherapy
- Non-equilibrated diabetes
- Long-term steroid use
- Immunodepression
- Chronic hepatitis with ascitis

Risk of exposure, infection

- Per-op (important) vesical or rectal injury

Risk of fistula

Relative contra-indications for synthetic prosthesis

- Pre-operative sexual activity

Risk of dyspareunia up to 15%

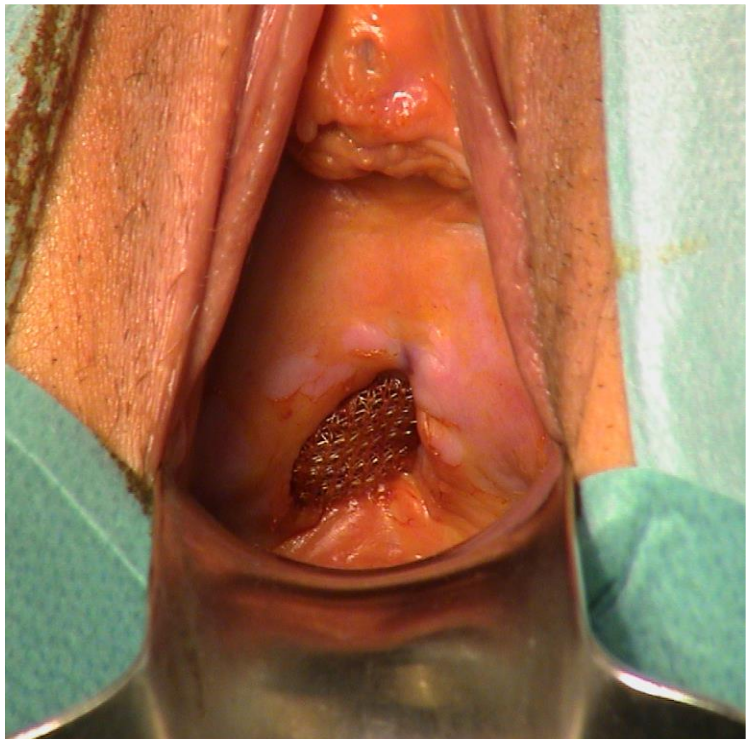
- Current tabacco use
- Concomittant hysterectomy

Risk of exposure

- Associated posterior mesh

Not enough evidence

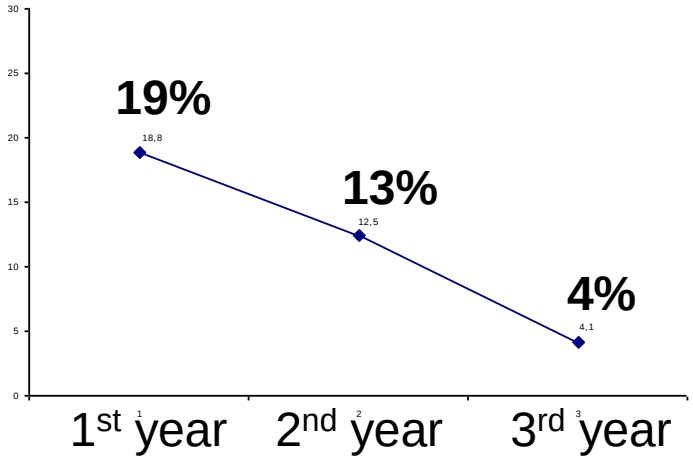
HOW TO DECREASE VAGINAL EXPOSURE?



- ✓ Do appropriate training
- ✓ Use only polypropylene monofilament macroporous
- ✓ Respect strict aseptia
- ✓ Avoid inverted T colpotomy
- ✓ Use a deep incision
- ✓ Avoid vaginal sulcus perforation
- ✓ Avoid concomitant hysterectomy
- ✓ Use smaller mesh
- ✓ Use Lighter mesh

SURGEON EXPERIENCE

- The learning curve

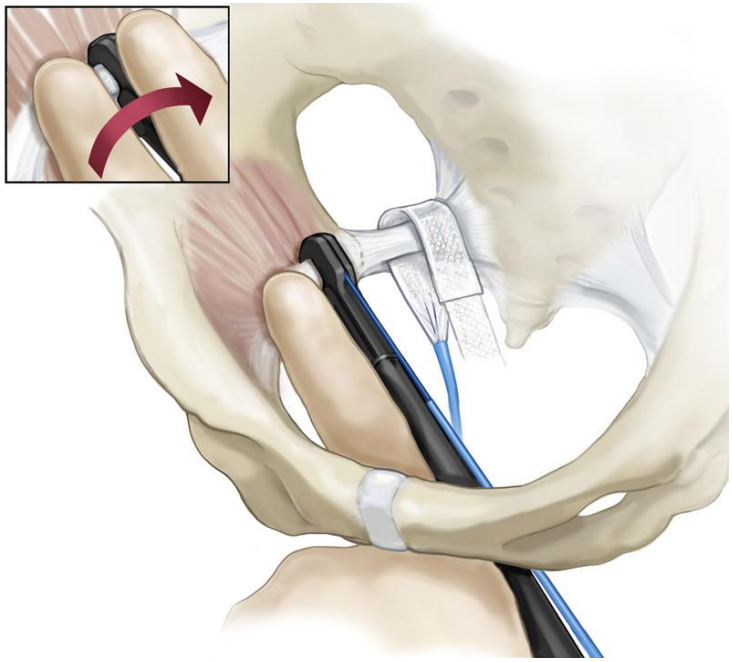


DWYER et al.
Br J Obstet Gynaecol 2005

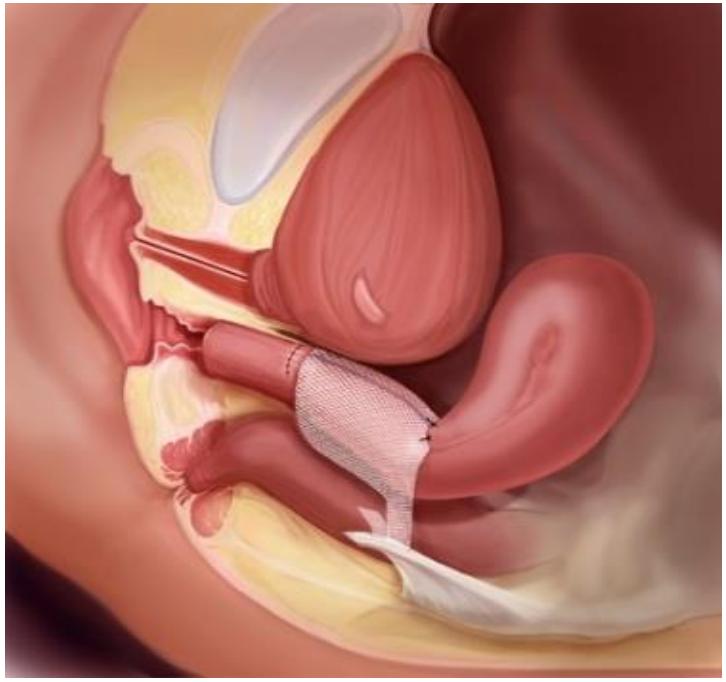
- Univariate logistic regression on 198 patients with 14 erosions (7.1%):
  Consultant vs fellow
  Erosion rates: 2.9% vs 15.6%
  OR 0.31 [95% CI 0.09-1.0] p=0.06

ACHTARI, DWYER et al., *Int Urogynecol J* 2005

Smaller mesh
with apical suspension



Exposure rates < 3%



Vu & Goldberg R et al, Int Urogynecol J 2011
de Tayrac et al., Eur J Obstet Gynecol 2012
Rivaux, de Tayrac et al., Prog Urol 2012

Lighter mesh (≤35 g/m2)

Surg Endosc (2013) 27:231–239
DOI 10.1007/s00464-012-2425-y

Randomized clinical trial of laparoscopic hernia repair comparing titanium-coated lightweight mesh and medium-weight composite mesh

- ✓ Recent RCT in hernia surgery
- ✓ Light (35g/m², Timesh®) vs medium-weight mesh (75g/m², Parietex®)

- ✓ Decreased post-op pain
- ✓ Return quickly to normal activities

- ✓ With no increased risk of recurrence at 2 years

Moreno-Egea A et al., Surg Endosc 2013

The future in 4 points

1. RESPECT INDICATIONS	✓ Recurrence after anterior repair or laparoscopic SCP ✓ Primary high stage anterior or anterior/apical POP
2. RESPECT CONTRA-INDICATIONS	✓ Women before 50 or after 80 years-old ✓ Tabacco use ✓ Previous post-operative infection / radiotherapy ✓ Non-equilibrated diabetes / long-term steroid use / immunodepression /chronic hepatitis with ascitis ✓ Intra-operative bladder or rectal injury
3. PREOP PATIENT INFORMATION	Give a pre-operative honest patient's information on: Risk / Benefit
4. RESPECT SURGICAL RULES	✓ Have enough surgical training and experience ✓ Use only polypropylene monofilament macroporous ✓ Respect strict aseptia ✓ Avoid inverted T colpotomy ✓ Perform a deep incision ✓ Avoid vaginal sulcus perforation ✓ Avoid concomitant hysterectomy