W11: Progress and controversies in vaginal prolapse surgery: audience survey and case studies

Workshop Chair: Nikolaus Veit-Rubin, Austria
12 September 2017 11:00 - 12:30

Start	End	Topic	Speakers
11:00	11:10	Introduction: The FDA Aftermath	Nikolaus Veit-Rubin
11:10	11:15	Case study: Mesh complication	All
11:15	11:20	Questions	None
11:20	11:35	Native tissue repair: Tradition and Evidence about efficiency	Heinz Kölbl
11:35	11:40	Case study: Native tissue repair	All
11:40	11:55	New materials in mesh surgery: Evolution, primary results and ongoing trials	Renaud De Tayrac
11:55	12:00	Case study: Trans vaginal mesh repair	All
12:00	12:15	Vaginal prolapse surgery: To mesh or not to mesh? - Current evidence	Alex Digesu
12:15	12:20	Case study: What to do for primary repair	All
12:20	12:30	Discussion	All

Speaker Powerpoint Slides

Please note that where authorised by the speaker all PowerPoint slides presented at the workshop will be made available after the meeting via the ICS website www.ics.org/2017/programme Please do not film or photograph the slides during the workshop as this is distracting for the speakers.

Aims of Workshop

There has been intense debate about the use of synthetic meshes in vaginal prolapse surgery given the existence of a highly efficient alternative, which is traditional native tissue repair. Although a graft inlay seems to reduce the risk of recurrence, a main complication related to its use is erosion in the vagina. In 2011, after the FDA warning, many transvaginal meshes were voluntarily withdrawn from the market under economic and juridical pressure and the debates were increasingly dominated by emotion rather than scientific facts. Although there is a decrease in the use of meshes, there has been significant improvement in the quality of material with promising results in the hands of skilled surgeons familiar with traditional techniques

Learning Objectives

- Detail the different techniques of native and prothetic vaginal prolapse surgery.
- Provide an update on the newest available evidence in both native tissue repair and transvaginal mesh surgery
- Engage a factual debate based on case studies between the panel and the audience and assess the change of habits in participants before and after the workshop

Learning Outcomes

Identify what is myth and reality regarding risks and benefits of both native tisue repair and transvaginal mesh surgery

Target Audience

Urogynaecologists and Urologists with an activity in vaginal prolapse surgery

Advanced/Basic

Advanced

Nikolaus Veit-Rubin, Gynecologist, Department of Gynecology and Obstetrics, Medical University Vienna, Austria

There has been intense debate about the use of synthetic meshes in vaginal prolapse surgery given the existence of a highly efficient alternative, which is traditional native tissue repair. Although a graft inlay seems to reduce the risk of recurrence, a main complication related to its use is erosion in the vagina. Despite initially reassuring data, concerns regarding the safety of transvaginal meshes arose in 2008 with the first FDA notification that it had received more than 1,000 reports of mesh associated complications, some of which may not be correctable surgically. In 2011, the FDA released two more communications highlighting safety concerns surrounding meshes. The update stated that there were 1,503 reported complications associated with mesh devices for POP from 2008 to 2010. The most common complications included mesh erosion through the vagina, pain, infection, bleeding, dyspareunia, organ perforation, and urinary problems. There were also reports of recurrent prolapse, neuromuscular problems, vaginal scarring with shrinkage, and emotional distress. Many of these complications required further surgical intervention. Subsequently, many transvaginal meshes were voluntarily withdrawn from the market under economic and juridical pressure and the debates were increasingly dominated by emotion rather than scientific facts. Although there is a decrease in the use of meshes, there has been significant improvement in the quality of material with promising results in the hands of skilled surgeons familiar with traditional techniques. There is a need to deconstruct the myths around both native repair and mesh surgery and to return to a debate based on evidence.

Heinz Kölbl, Gynecologist , Department of Gynecology and Obstetrics, Medical University Vienna, Austria

There is a wide variety of highly efficient surgical procedures available for native tissue prolapse repair. This indicates that there is a lack of consensus as to the optimal surgical approach.

There is growing recognition that adequate support for the vaginal apex is an essential component of a durable surgical repair for women with advanced prolapse. Because of the significant contribution of the apex to anterior vaginal support, the best surgical correction of the anterior and posterior walls may fail unless the apex is adequately supported. Vaginal surgical correction of the apex has several good options with relatively high success rates such as sacrospinous ligament suspension, uterosacral ligament suspension or McCall's culdoplasty. The individual woman's surgical history and goals, as well as her individual risks of surgical complications, prolapse recurrence and de novo symptoms affect surgical planning and the choice of procedure.

Renaud De Tayrac, Gynecologist, Department of Gynecology and Obstetrics, CHU Nimes, France

The principle of using grafts in reconstructive surgery is to reinforce existing tissue. The material must be safe, biologically compatible, and must provide both anatomic and functional results. The ideal material should be chemically and physically inert, non-carcinogenic, mechanically strong while remaining flexible, non-allergenic, non-inflammatory, and non-modifiable by body tissue. It must be sterile, convenient to use and affordable, with minimal risk of subsequent infection or rejection. Currently, no graft has all these properties. Moreover, in POP surgery, the optimal implant should restore normal anatomy and function to the vagina and the surrounding pelvic organs and have longer longevity than autologous tissue. Once implanted, it should not result in adhesion formation on the visceral surfaces. The ideal mesh should incur minimal inflammatory reaction, followed by vascular and fibroblastic ingrowths. The histological host response to reconstructive material comprises several stages:

- The incorporation by host cells, allowing neovascularization and collagen deposition.
- The encapsulation by collagen and connective tissue deposit at the periphery of the material.
- The resorption when material is replaced by host neo-connective tissue.

Host response depends on absorbability, pore size (space between filaments), weave (mono or multifilament), and weight (density). Both absorbable and non-absorbable meshes cause initial and chronic inflammatory reactions after implantation. Recent efforts have led to the development of macroporous, lightweight meshes, widely possessing the characteristics mentioned above with promising preliminary results in ongoing studies.

Alex G. Digesu, Urogynaecologist, Department of Urogynaecology, St. Mary´s Hospital, Imperial College London, UK

While transvaginal permanent mesh is associated with lower rates of awareness of prolapse, repeat surgery for prolapse, and prolapse on examination than native tissue repair, it is also associated with higher rates of repeat surgery for prolapse or stress urinary incontinence or mesh exposure (as a composite outcome), and with higher rates of bladder injury at surgery and de novo stress urinary incontinence.

The risk-benefit profile means that transvaginal mesh has limited utility in primary surgery. While it is possible that in women with higher risk of recurrence the benefits may outweigh the risks, there is currently no evidence to support this position. Limited evidence suggests that absorbable mesh may reduce rates of recurrent prolapse on examination compared to native tissue repair. Newer transvaginal meshes should be utilised under the discretion of the ethics committee.

Suggested Learning before Workshop Attendance

Atlas of Pelvic Anatomy and Gynecologic Surgery, 4th Edition by Michael S. Baggish MD FACOG (Author), Mickey M. Karram MD (Author)

Suggested Reading

1. Margulies RU, Lewicky-Gaupp C, Fenner DE, McGuire EJ, Clemens JQ, Delancey JO. Complications requiring reoperation following vaginal mesh kit procedures for prolapse. Am J Obstet Gynecol. 2008;199(6):678 e1-4.
2. Jonsson Funk M, Edenfield AL, Pate V, Visco AG, Weidner AC, Wu JM. Trends in use of surgical mesh for pelvic organ prolapse. Am J Obstet Gynecol. 2013;208(1):79 e1-7.
3. Maher C, Feiner B, Baessler K, Schmid C. Surgical management of pelvic organ prolapse in women. Cochrane Database Syst Rev. 2013(4):CD004014.
4. Paz-Levy D, Yohay D, Neymeyer J, Hizkiyahu R, Weintraub AY. Native tissue repair for central compartment prolapse: a narrative review. Int Urogynecol J. 2016.
5. Glazener CM, Breeman S, Elders A, Hemming C, Cooper KG, Freeman RM, et al. Mesh, graft, or standard repair for women having primary transvaginal anterior or posterior compartment prolapse surgery: two parallel-group, multicentre, randomised, controlled trials (PROSPECT). Lancet. 2016.
6. Barber MD, Maher C. Apical prolapse. Int Urogynecol J. 2013;24(11):1815-33.
7. Chen CC, Ridgeway B, Paraiso MF. Biologic grafts and synthetic meshes in pelvic reconstructive surgery. Clinical obstetrics and gynecology. 2007;50(2):383-411.
8. Ridgeway B, Chen CC, Paraiso MF. The use of synthetic mesh in pelvic reconstructive surgery. Clinical obstetrics and gynecology. 2008;51(1):136-52.
9. Gutman RE, Rardin CR, Sokol ER, Matthews C, Park AJ, Iglesia CB, et al. Vaginal and laparoscopic mesh hysteropexy for uterovaginal prolapse: a parallel cohort study. Am J Obstet Gynecol. 2016.

WIFI: ICS-2017

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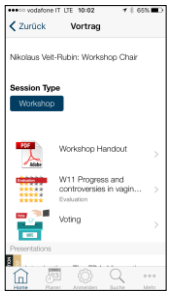
APP Voting



ICS

WORKSHOP 11
Progress and controversies in vaginal prolapse surgery

VAGINAL MESH SURGERY
"The FDA AFTERMATH"

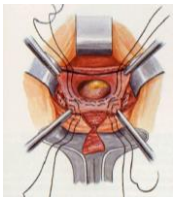
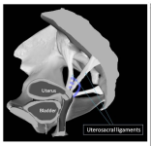
Nikolaus Veit-Rubin
MEDIZINISCHE UNIVERSITÄT WIEN

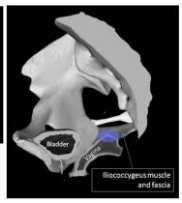
No disclosures

Background

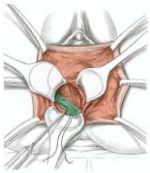
- **lifetime risk of between 12% and 19%** of undergoing surgery for POP
- USA ~**150,000** women undergo surgery for (POP) each year
- During 2012, > **680,000** POP procedures were performed in 15 (OECD) countries (20% apical compartment repairs)
- This number is projected to **increase dramatically by ~48 %** over the next 40 years
- In 2006: 1/3 of surgeries involved mesh,

Smith FJ et al, Obstet Gynecol 2010
Wu JM et al, Am J Obstet Gynecol 2011.
Haya N et al, Am J Obstet Gynecol 2015







Recurrence in Native Tissue repair

- **high recurrence rates**, mu

Yes, BUT...

- Most surgeons conduct the operation with a **low frequency**
- Results based on **subjective symptoms**
- POP operating **techniques and surgical traditions vary considerably** between surgical centers and countries
- **No standardized definitions** of cure following POP repairs

- risk of reoperation for POP recurrence in native reconstructive surgery lower than previously estimated, being **close to 10%**

Oversand SH et al, Int Urogynecol J 2014
Salvatore S et al, Neurourol Urodyn 2009
Nüssler E. et al, Int Urogynecol J J 2017

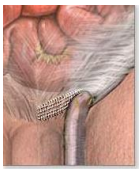
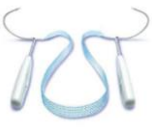
The rationale behind the use of mesh

- **potential reduction of the high recurrence** rates after native tissue
- **reinforce muscles and ligaments** of the pelvic floor

Criteria:
- biologically safe,
- chemically and physically inert,
- non-carcinogenic
- mechanically solid
- allowing extension flexibility.
- not initiate any allergic or inflammatory response

History

- 1970 with abdominal hernia repair
- **Good results with suburethral tapes**
- 2004 FDA clearance for transvaginal POP surgery
- Classified as **class II (moderate risk)**
- 510(k) clearance, which bypasses clinical trials and requires manufacturers only to show that their product is substantially equivalent to one already on the market.
- **More than 40 companies** began the manufacturing of mesh devices in the 10 years following the initial cleared device

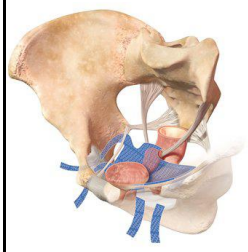
Parsons, Clin Obstet Gynecol 2002
Parsons M, J Brit Men Soc 2005

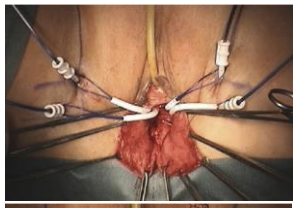
Mesh types

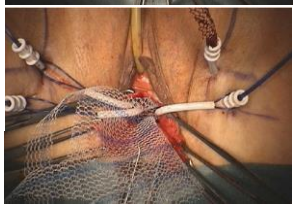
- **autografts** from fascia lata or the rectum,
- **allografts** from human cadavers,
- **xenografts** from bovine or porcine material
- **synthetic grafts**
  - polyester
  - polypropylene.
  - absorbable or non-absorbable

- Classification by
  pore size, weight and structure (mono or multifilament)

Type of mesh	Characteristics
I	Macroporous (.75 microns) and monofilamentous such as polypropylene It is further divided into heavy-, mid-, and light-weight materials (eg, Prolene®).
II	Microporous (.10 microns) such as polytetrafluoroethylene (eg, Gore-Tex®).
III	Macroporous material (.75 microns) with either multifilamentous or microporous components such as polyethylene (eg, Mersilene®). This category includes some polypropylene materials with microporous components such as Ob Tape® and IVS Tunneler®
IV	Submicronic (pore size ,1 micron) (eg, polypropylene sheet Cellgard®) and associated with type I mesh for adhesion prevention.







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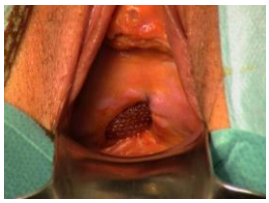
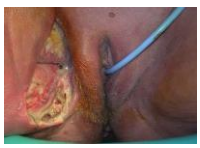
Mesh-related complications

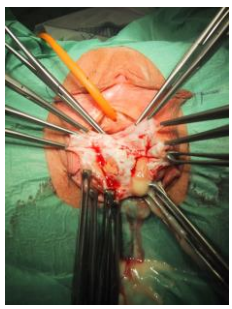
"Requiring multiple operative interventions
(median of 2 surgeries per patient)"

- Recurrence
- Vaginal **erosion/extrusion**
- Erosion/extrusion into the bladder/urethra/bowel
- Dyspareunia
- Neuralgia
- Shrinkage
- Infection (local and systemic)

Marquilies et al, Am J Obstet Gynecol 2008







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1st warning about increased adverse events

2008

29. September 2017

U.S. Food and Drug Administration

Home > Medical Devices > Medical Device Safety > Alerts and Notices (Medical Devices)

Medical Devices

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

Complications reported:

- 1000 reports of complications 2005-2007
- Complications **rare**, but can be **serious**
- Most common: mesh extrusion, infection, pain, urinary problems, dyspareunia
- In some cases, led to significant decrease in QOL
- Factors: health, mesh type/size, technique, other procedures, estrogen status

U.S. Food and Drug Administration

Home > Medical Devices > Medical Device Safety > Alerts and Notices (Medical Devices)

Medical Devices

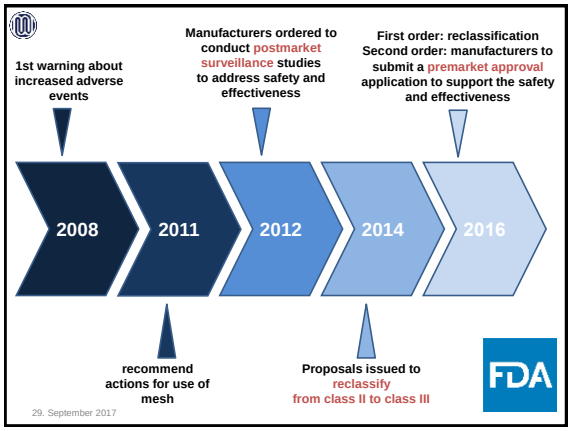
FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence

Issued: October 20, 2008

Recommendations:

- ✓ Need **specialized training** for mesh placement kit
- ✓ Be aware of the risks
- ✓ Notify patients mesh is permanent
- ✓ Understand and communicate to your patients that complications can occur and may not resolve with further surgery *(pain, dyspareunia, scarring, narrowing of the vagina and QOL issues)*
- ✓ Provide patients **proper consent** and a copy of manufacturer IFU *(Instructions for Use)*

4



Johnson & Johnson

FAMILY OF MEDICAL DEVICE & DIAGNOSTIC COMPANIES

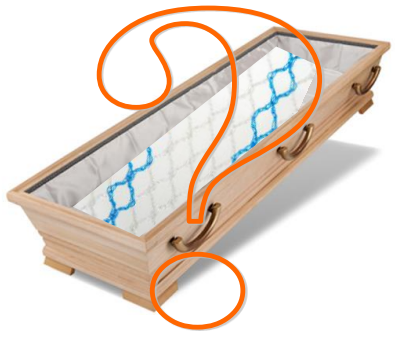
Please Join the Following
Conference Call with Ethicon Gynecare

in relation to the Discontinuation of Certain
Ethicon, Gynecare Pelvic Floor Products

19:00 – 20:00 CET
Conference ID: 89426793

Facilitated by Zeb Viana, Director Gynecare EMEA &World Wide Medical Affairs Director Piet Hinoul

29. September 2017



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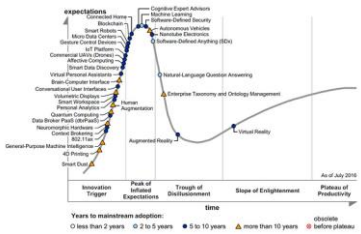
Innovation adaptation curve

depictions of how a technology or application will evolve over time



THE HYPE CYCLE

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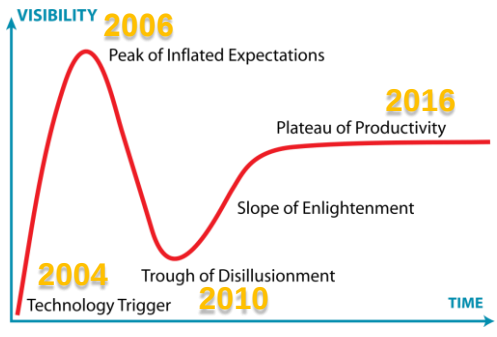
Gartner

Mesh Hype Cycle



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Iglesia C. et al, OBG Management 2013

To mesh or not to mesh?

Thank you for your attention!

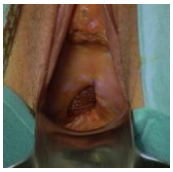
IUGA
international urogynecological association

ICS WORKSHOP 11
Progress and controversies in vaginal prolapse surgery

CASE STUDY 1

MEDIZINISCHE UNIVERSITÄT WIEN

Exposure

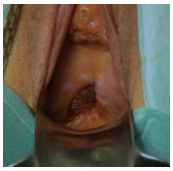


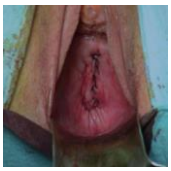
Question

How would you have managed this complication?

1. Attempting to remove the mesh entirely and instant native POP repair
2. Partial removal and instant native POP repair
3. Total or partial removal of the mesh material and secondary repair
4. Wait and see – topic treatment (NSAID, estrogen?)

Exposure

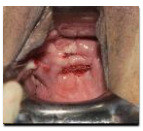




Mrs K., 56 y.o.

- 3 vaginal deliveries
- Prolapse symptoms for 2 years (« dragging », « pressure »)
- Sexually active – no dyspareunia
- Treated by **Elevate® posterior**

- ✓ GH 4 cm
- ✓ Simplified POP-Q : POP stage 2
  - ✓ Ba : -2 cm
  - ✓ C : -2 cm
  - ✓ Bp : +1 cm



2 months AFTER SURGERY:

- Dyspareunia, « hispareunia »
- Discharge
- No Prolapse symptoms
- No LUTS

Question

How would you have managed this complication?

1. Attempting to remove the mesh entirely and instant native POP repair
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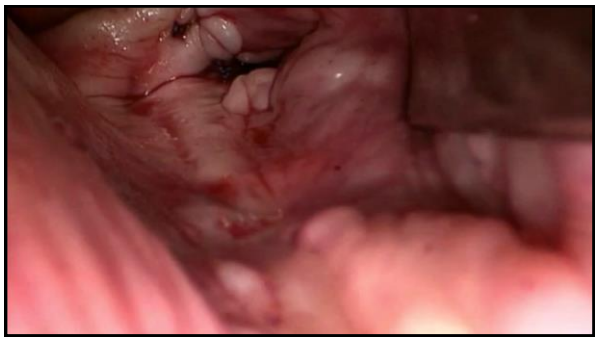
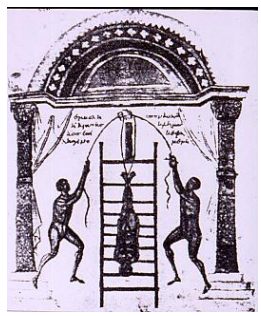


Vaginal Prolapse Surgery with Native Tissue Repair

Univ. Prof. Dr. Dr. h.c. Heinz Koelbl
Department of General Gynaecology and Gynaecological Oncology
Medical University of Vienna

Disclosures

- International Advisory Board Astellas
- International Advisory Board Pfizer
- International Advisory Board American Medical Systems
- Takeda International Advisory Board
- Consultant Johnson & Johnson



Lifetime Risk of Undergoing Surgery for Pelvic Organ Prolapse

Fiona J. Smith, BHlthSc(Hons), C. D'Arcy J. Holman, MPH, PhD, Rachael E. Moorin, PhD, MMRS, and Nicolas Tsokos, MBBS, FRANZCOG, CU

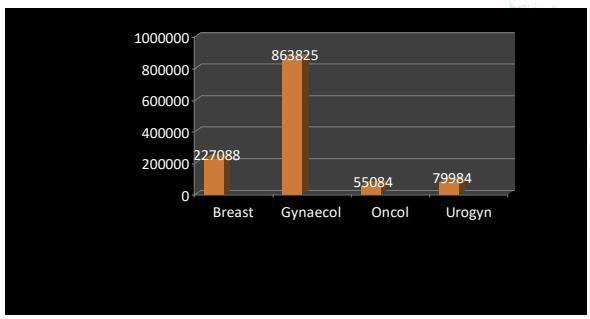
VOL. 116, NO. 5, NOVEMBER 2010 OBSTETRICS & GYNECOLOGY

RESULTS: The lifetime risk of surgery for POP in the general female population was 19% based on the most recent cross-sectional rates, a figure higher than the 11–12% reported from U.S. managed-care populations.

CONCLUSION: There is a relatively high likelihood that a woman in Western Australia will undergo surgery for POP during her lifetime. If, as our results suggest, the burden of genital prolapse in general populations is higher than previously thought, there is justification for a stronger evidence base for prevention, early detection and intervention to reduce the personal and societal costs of these gynecological conditions.
(Obstet Gynecol 2010;116:1096–1100)

LEVEL OF EVIDENCE: II

80.000 Interventions for PFR- and Incontinence Surgery per year in Germany



www.g-drg.de 2008

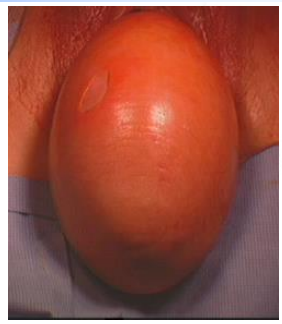
Time - primary and recurrent intervention

Surgery	n Pts	yrs
HE - 1. Op.	115	19,3
1. Op. - 2. Op	107	12,5
2. Op. - 3. Op.	33	4,6
3. Op. - 4. Op.	11	3,2
4. Op. - 5. Op.	2	1,5

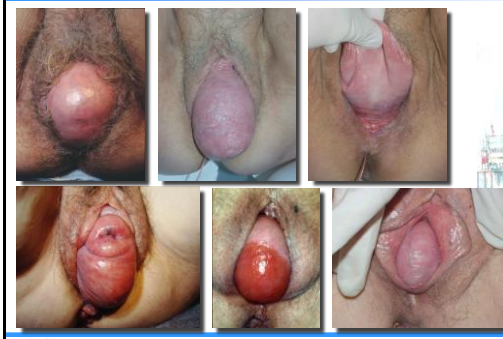
Olsen A. et al.: Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. Obst Gynec.(1997)

Aims of pelvic floor reconstructive surgery

- **Restoration of topography**
- **with respect to function of:**
  - ✓ **Bowel**
  - ✓ **Bladder**
  - ✓ **Sexuality**



Various forms of Prolapse



urogynecology

anterior compartment

anterior repair/ paravaginal repair
continence-surgery – sling, colposuspension, bulking agents

middle compartment

abdominal hysterectomy ± sacrocolpopexy
vaginal hysterectomy ± sacrospinous/ iliococcygeus fixation
abdominal or vaginal sacrospinous fixation/ sacrohysteropexy

posterior compartment

posterior repair
rectopexy
anal sphincter repair

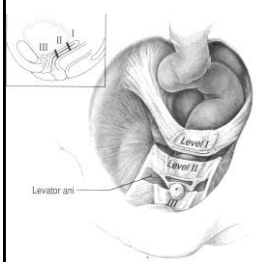
Surgical options

ANTERIOR → Anterior colporrhaphy

APICAL
- WITH Vaginal Hysterectomy
  - McCall Culdoplasty
  - Sacrospinous fixation (Richter)
  - Uterosacral fixation (Shull)
- WITHOUT Vaginal Hysterectomy
  - Sacrospinous fixation (Richardson)
  - Manchester procedure

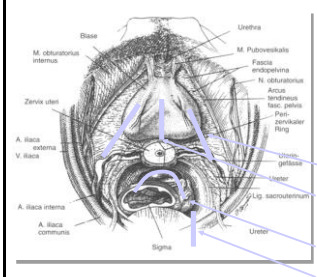
POSTERIOR → Posterior colporrhaphy

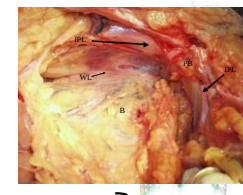
Urogynaecological implications



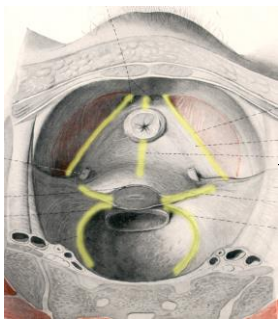
- **Level I: Utero-Sacral and cardinal ligaments**
- **Level II: Pubo-cervical Fascia & Recto-vaginal Septum**
- **Level III: pubo-vesical ligaments and perineal body**

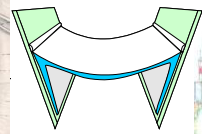
PFR – tissue specific repair





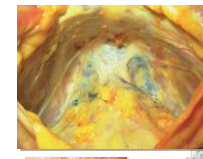
lateral defects
central defects } *anterior defects*
middle defects
posterior defects

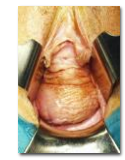


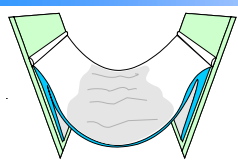


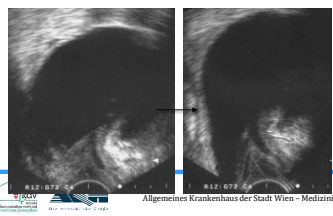
Central Defect vs. Lateral Defect

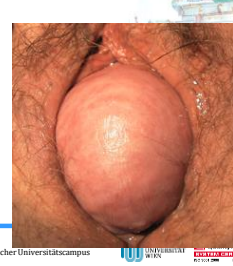
Distension Cystocele **Tractions cystocele**

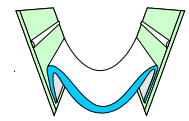


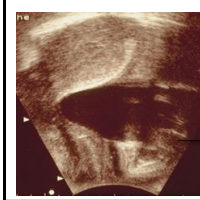


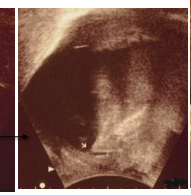


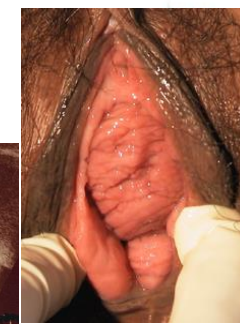






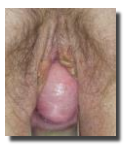


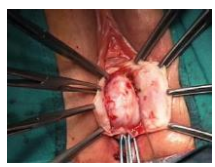


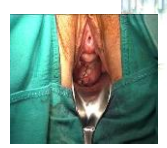


Anterior repair

- Indication: central anterior defect







The NEW ENGLAND JOURNAL of MEDICINE

MAY 12, 2011

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 women: 200 mesh vs 189 traditional colporrhaphy

	Mesh	Colporraphy	P-v
Objective cure rate	60.8%	34.5%	<0.001
Operation time (min)	33.5	52.6	<0.001
Blood loss (ml)	35.4	84.7	<0.001
Bladder perforation	3.5%	0.5%	0.07
New SUI	12.3%	6.3%	0.05
Revision for mesh exposure	3%	0	0.03

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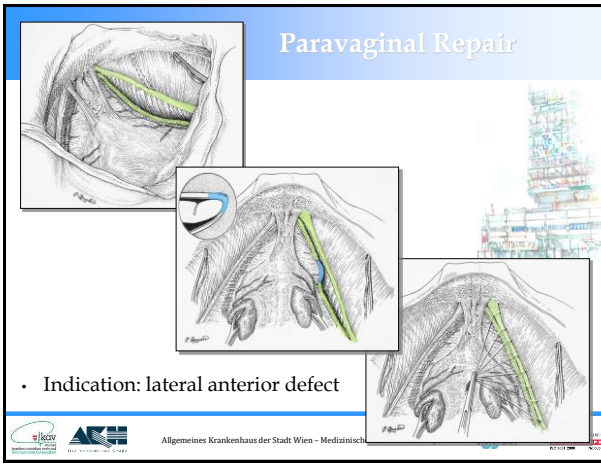
389 women: 200 mesh vs 189 traditional colporrhaphy

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.

Paravaginal Repair

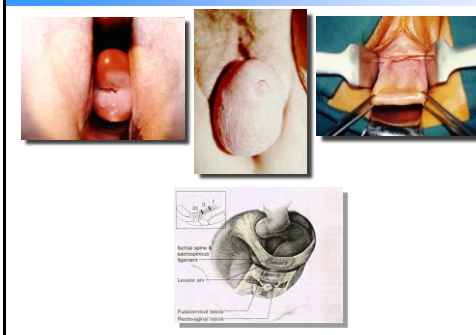


- Indication: lateral anterior defect

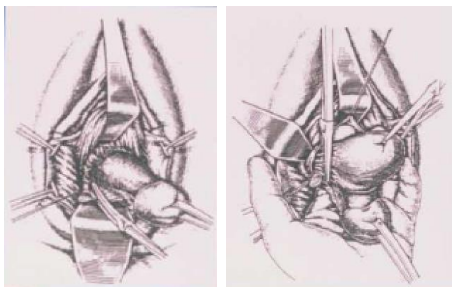
Results paravaginal defect repair

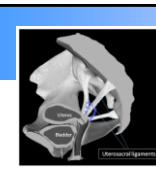
	n	Cystocele cured (%)	GSI cured (%)
Richardson et al.	60	97	92
Baden & Walker	173	78	84
Shull & Baden	149	95	97
Ball	200	96	96
Richardson	800	95	95
Shull et al	62	76	93
Milani et al	109	91	83

Defect repair – middle compartment

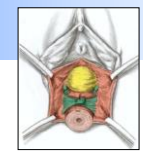


Vaginal hysterectomy

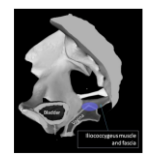




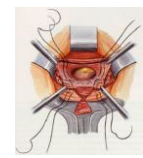
Uterosacral Fixation



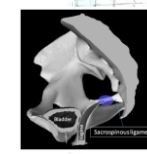
Manchester procedure



Iliococcygeus fixation

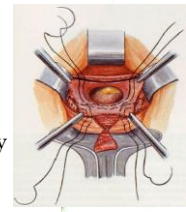


McCall Culdoplasty



Sacrospinous Fixation

Mc Call Culdoplasty

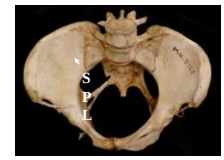


- the most common preventive procedure for apical prolapse
- usually performed during hysterectomy
- objective recurrence 4–9 years after surgery 15 %
- anterior vaginal recurrence rate of 6 %
- 82 % satisfaction rate with few complications
- objective vaginal shortening without significant impact on sexual function

Paz-Levy et al, Int Urogyn J 2017

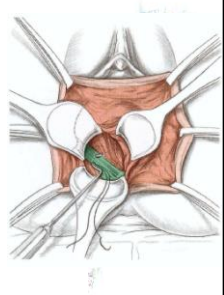
Sacrospinous fixation (Richter)

- Simple approach
- Technique providing maintenance of sexual function
- Achieves adequate vaginal length and width
- Combined reconstructive procedures possible
- Additional Incont. Surg.feasible
- Regional anesthesia



Sacrospinous fixation (Richter)

- unilaterally or bilaterally
- rates of 2.4– 19 % for anatomical recurrence
- anterior wall as the most frequent site of recurrence (21.3 %)
- most often as an asymptomatic recurrence, which requires treatment only in 3–5 %
- Few studies focused on functional results
- satisfaction rates of 89.7 %

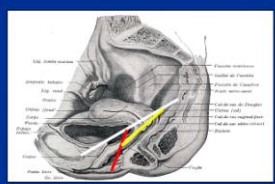


Sacrospinous fixation of the vagina

Author	n Pts	follow-up mths	Rec.	%
Paraiso	243	36	20	8,2
Albrich	216	48	5	3,2
Imparato	179	55	4	2,6
Nichols	163	36	5	3,1
Penalver	160	60	10	6,2
Pasley	156	44	8	5,6
Chapin	134	48	5	4,5
Morley	100	36	3	3,3
Veronikis	71	58	0	0
Monk	69	61	1	1,6
Carey	64	63	1	1,5
Backer	51	51	0	0
Cruikshank	48	48	1	2
Koelbl	200	60	4	3,2
TOTAL:	1854	47	67	3,2

Comparaison IRM

Mesures IRM de l'axe vaginal en post-opératoire



Axe physiologique
53° / 145°

Après promontofixation

57° / 137°

Après Richter

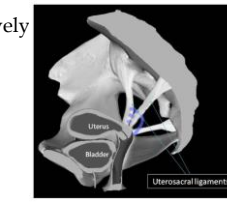
54° / 220°

SZE et al., *Int Urogynecol J* 2001

Slide from Prof. R. De Tayrac

Uterosacral Fixation

- avoids the retroflexion seen after SSLF
- Surgical failure was found in 15.3 % (composite of anatomical and clinical)
- 20.6 % de novo dyspareunia
  70 % successfully treated conservatively
- Urinary tract infection (UTI) in 14 %



Paz-Levy et al, Int Urogyn J 2017

OPTIMAL Trial

Research

JAMA
The Journal of the American Medical Association

Original Investigation

Comparison of 2 Transvaginal Surgical Approaches and Perioperative Behavioral Therapy for Apical Vaginal Prolapse
The OPTIMAL Randomized Trial

Matthew D. Barber, MD, MHS; Linda Brubaker, MD; Kathryn L. Burgio, PhD; Holly E. Richter, PhD, MD; Ingrid Nygaard, MD; Alison C. Weidner, MD; Shawn A. Menefee, MD; Emily S. Lukacz, MD; Peggy Norton, MD; Joseph Schaffer, MD; John N. Nguyen, MD; Diane Borello-France, PhD; Patricia S. Goode, MD; Sharon Jakus-Waldman, MD; Cathie Spino, ScD; Lauren Klein Warren, MS; Marie G. Gantz, PhD; Susan F. Meikle, MD; for the Eunice Kennedy Shriver National Institute of Child Health and Human Development Pelvic Floor Disorders Network

CONCLUSIONS AND RELEVANCE Two years after vaginal surgery for prolapse and stress urinary incontinence neither ULS nor SSLF was significantly superior to the other for anatomic, functional, or adverse event outcomes. Perioperative BPMT did not improve urinary symptoms at 6 months or prolapse outcomes at 2 years.

Laparoscopic sacrocolp

ncbi.nlm.nih.gov/pubmed/28417153

Format: Abstract — Send to

Int Urogynecol J. 2017 Apr 17. doi: 10.1007/s00192-017-3296-5. [Epub ahead of print]

Laparoscopic sacrocolpopexy compared with open abdominal sacrocolpopexy for vault prolapse repair: a randomised controlled trial.

Coolen AWM[1,2], van Oudheusden AMJ[3], Mol BWJ[4,5], van Eijndhoven HWF[6], Roovers JWR[7], Bongers MY[3,8].

Author information

Abstract

INTRODUCTION AND HYPOTHESIS: The objective was to evaluate the functional outcome after laparoscopic sacrocolpopexy versus open sacrocolpopexy in women with vault prolapse.

METHODS: A multicentre randomised controlled trial was carried out at four teaching and two university hospitals in the Netherlands in women with symptomatic vault prolapse requiring surgical treatment. Participants were randomised for laparoscopic or open sacrocolpopexy. Primary outcome was disease-specific quality of life measured using the Urinary Distress Inventory (UDI) questionnaire at 12 months' follow-up. Secondary outcomes included anatomical outcome and perioperative data. We needed 74 participants to show a difference of 10 points on the prolapse domain of the UDI 12 months after surgery (power of 80%, α error 0.05).

RESULTS: Between 2007 and 2012, a total of 74 women were randomised. Follow-up after 12 months showed no significant differences in domain scores of the UDI between the two groups. After 12 months, both groups reported a UDI score of 0.0 (IQR: 0-0) for the domain "genital prolapse", which was the primary outcome. There were no significant differences between the two groups (p = 0.93). The number of severe complications was 4 in the laparoscopic group versus 7 in the open abdominal group (RR 0.57; 95% CI 0.50-2.27). There was less blood loss and a shorter hospital stay after laparoscopy: 2 (IQR 2-3) versus 4 (IQR 3-5) days, which was statistically different. There was no significant difference in anatomical outcome at 12 months.

CONCLUSION: Our trial provides evidence to support a laparoscopic approach when performing sacrocolpopexy, as there was less blood loss and hospital stay was shorter, whereas functional and anatomical outcome were not statistically different.

KEYWORDS: Pelvic organ prolapse; Sacral colpopexy; Sacrocolpopexy; Vault prolapse

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Laparoscopic sacrocolp

Laparoscopic sacrocolpopexy versus vaginal sacrospinous fixation for vaginal vault prolapse, a randomized controlled trial: SALTO-2 trial, study protocol.

Author information

Abstract

BACKGROUND: Hysterectomy is one of the most performed surgical procedures during lifetime. Almost 10 % of women who have had a hysterectomy because of prolapse symptoms, will visit a gynaecologist for a surgical correction of a vaginal vault prolapse thereafter. Vaginal vault prolapse can be corrected by many different surgical procedures. A Cochrane review comparing abdominal sacrocolpopexy to vaginal sacrospinous fixation considered the open abdominal procedure as the treatment of first choice for prolapse of the vaginal vault, although operation time and hospital stay is longer. Literature also shows that hospital stay and blood loss are less after a laparoscopic sacrocolpopexy compared to the abdominal technique. To date, it is unclear which of these techniques leads to the best operative result and the highest patient satisfaction. Prospective trials comparing vaginal sacrospinous fixation and laparoscopic sacrocolpopexy are lacking. The aim of this randomized trial is to compare the disease specific quality of life of the vaginal sacrospinous fixation and laparoscopic sacrocolpopexy as the treatment of vaginal vault prolapse.

METHODS: We will perform a multicentre prospective randomized controlled trial. Women with a post-hysterectomy symptomatic, POP-Q stage ≥2, vaginal vault prolapse will be included. Participants will be randomized to the vaginal sacrospinous fixation group or the laparoscopic sacrocolpopexy group. Primary outcome is disease specific quality of life at 12 months follow-up. Secondary outcome will be the effect of the surgical treatment on prolapse related symptoms, sexual functioning, procedure related morbidity, hospital stay, post-operative recovery, anatomical results using the POP-Q classification after one and 5 years follow-up, type and number of re-interventions, costs and cost-effectiveness. Analysis will be performed according to the intention to treat principle and not as a per protocol analysis. With a power of 90% and a level of 0.05, the calculated sample size necessary is 96 patients. Taking into account 10% attrition, a number of 106 patients (53 in each arm) will be included.

DISCUSSION: The SALTO-2 trial is a randomized controlled multicentre trial to evaluate whether the laparoscopic sacrocolpopexy or vaginal

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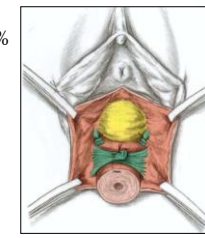
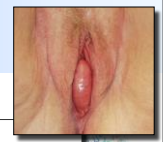
Manchester procedure

- Traditional uterine-preserving procedure
- Reoperation rate up to 21 % at 6–12 years
- Unique complication: cervical stenosis rate of 11.3 %
- Fertility impairment
- Dyspareunia
- Miscarriage rate up to 50%

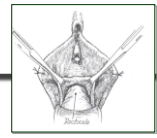


Williams et al, Am J Obstet Gynecol 1966
O'Leary et al, Am J Obstet Gynecol 1970
Tipton J et al, Obstet gynecol br commonw 1970
Paz-Levy et al, Int Urogyn J 2017

Posterior colporrhaphy



Author		Follow-up	Obstipation	Rec.
Mellgren	1995	postop.	48%	-----
Infantino	1995	36 Mo		25%
Cundiff	1998	12 Mo		8%



Conclusion

- **scarcity of studies** reporting functional outcomes
- overall **high rate of efficacy for native tissue repair** procedures
- **low complication, recurrence**, and retreatment rates.
- risks and benefits balance
- overall goals should be part of the **decision-making process**
- Research should focus on prospective studies with long-term functional outcomes Using **questionnaires** for prolapse symptoms; urinary, defecatory, and sexual function

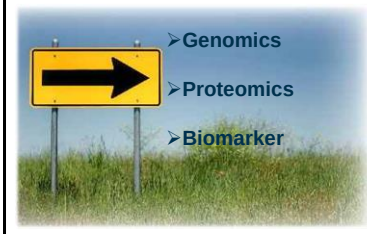
Traditional techniques – is there still a role in PFR surgery?

- According to EBM and guidelines – YES

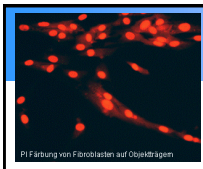
Cochrane Library

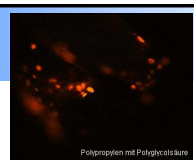
Cochrane Database of Systematic Reviews

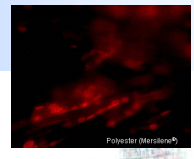
Perspectives in Urogynecology



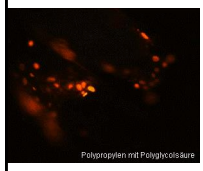
RISK GROUP ASSESSMENT

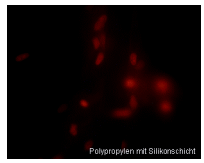


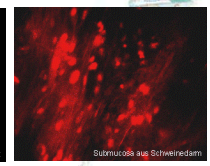




IN VITRO



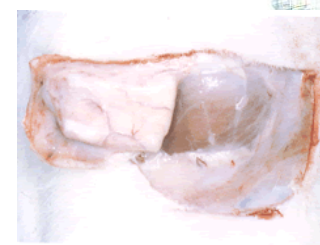




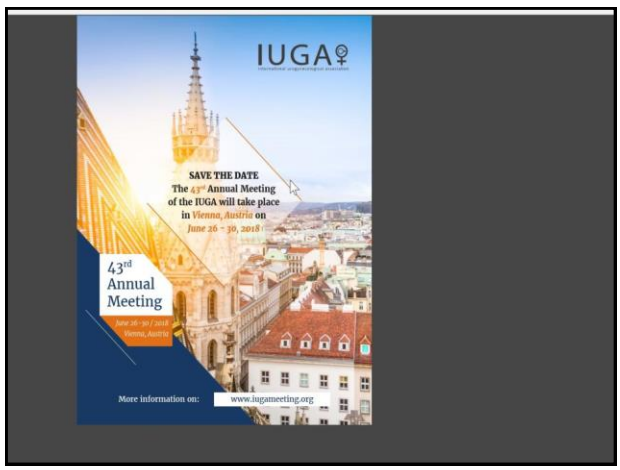
DNA – Fluorescence with Propriumiodide – day 8-10

Skala CE, Petry IB, Gebhard S, Hengstler JG, Albrich SB, Maltaris T, Naumann G, Koelbl H.
Mainz University Hospital, Department of Obstetrics & Gynecology, D-55131 Mainz, Germany. skala@uni-mainz.de.

IN VIVO



Skala et al.: Regen Med 2010



Thank you!

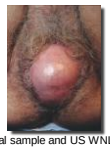
ICS WORKSHOP 11
Progress and controversies in vaginal prolapse surgery

CASE STUDY 2

MEDIZINISCHE UNIVERSITÄT WIEN

Mrs B., 61 y.o.

- 2 vaginal deliveries
- (unknown if prior cystocele repair)
- Prolapse symptoms for 3 years (« dragging », « pressure »)
- Sexually active – no dyspareunia
- No LUTS
- Thrombocytopenia



- ✓ GH 5 cm
- ✓ Simplified POP-Q : POP stage 2
  - ✓ Ba : 0 cm
  - ✓ C : +3 cm
  - ✓ Bp : +2 cm
- ✓ Elongated cervix
- ✓ Occult SUI

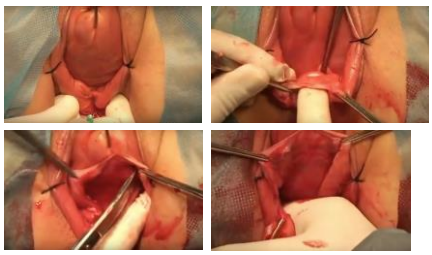
- cervical sample and US WNL
- Pessary treatment unsuccessful

Question

What surgical technique would you have chosen?

1. Vaginal hysterectomy and McCall culdoplasty or sacrospinous fixation
2. Uterus conserving treatment with site specific repair
3. Transvaginal Mesh surgery
4. Laparoscopic repair or other

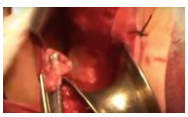
Uterus conserving sacrospinous fixation
Surgical steps



Posterior midline incision

Dissection close to the rectum to enter into the pararectal space

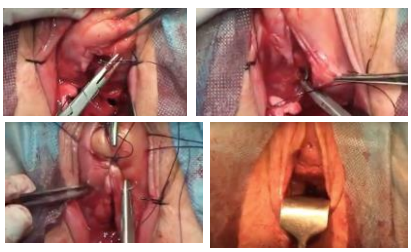
Uterus conserving sacrospinous fixation
Surgical steps



Identification and exposure of the sacrospinous ligament

Suture placement at the sacrospinous ligament

Uterus conserving sacrospinous fixation
Surgical steps



Suture placement at the level of the cervixs

Closure and Final result

ICS 2017 Florence
W11: Progress and controversies in vaginal prolapse surgery audience survey and case studies

New materials in mesh surgery:
Evolution, primary results and ongoing trials

R de TAYRAC, MD, PhD
Obs/Gyne Dept, CHU Caremeau, Nîmes, France

Disclosure

- Consultant for Boston Scientific
- Consultant for Coloplast
- ICS congress invitation by Astellas

Can vaginal mesh still be used? Current evidence – Cochrane 2016

37 RCTs (4023 women) – Only medium-weight (2nd generation) meshes

- ✓ Awareness of prolapse at one to three years was less likely after mesh repair (RR 0.66, 95% CI 0.54-0.81, 12 RCTs, n = 1614)
- ✓ Rates of repeat surgery for prolapse were lower in the mesh group (RR 0.53, 95% CI 0.31-0.88, 12 RCTs, n = 1675)
- ✓ More women in the mesh group required repeat surgery for the combined outcome of prolapse, SUI or mesh exposure (RR 2.40, 95% CI 1.51-3.81, 7 RCTs, n =867)

The newer, lightweight transvaginal permanent meshes (3rd generation) still available have not been evaluated within a RCT

Maher C et al., Int Urogynecol J 2016

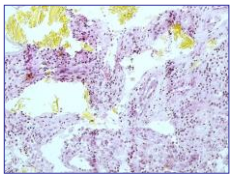
Mesh Classification regarding to the weight

✓ High weight mesh	> 80 g/m² (1st mesh generation)
✓ Medium weight mesh	50-80 g/m² (2nd mesh generation)
✓ Light mesh	< 35 g/m² (3rd mesh generation)

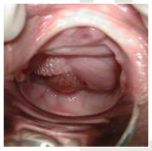
Earle DB et al., Surg Clin North Am 2008

✓ Ultra-light mesh	< 20-25 g/m²

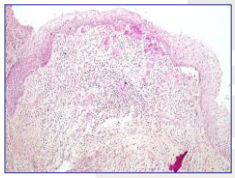
High weight mesh
1st generation (100 g/m²)



HES, x2O

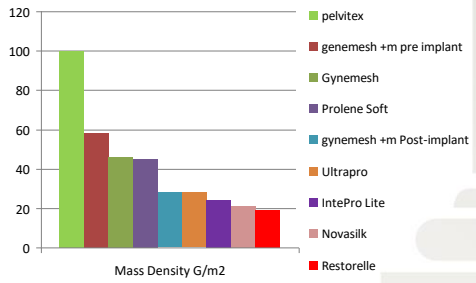


Marked Inflammatory response



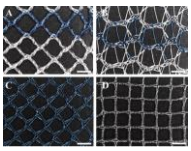
HES, x2,5

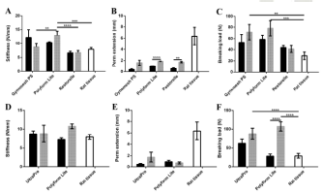
Evolution of mesh mass density over years



Basic science rational behind ultra-light meshes

		Mass/area (g/m²)
A	UltraPro	56±1 Medium weight
B	Gynemesh PS	40±0 Medium weight
C	Polyform Lite	26±0 Light mesh
D	Restorelle	19±0 Ultralight mesh



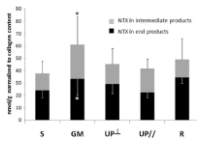


Ultralight mesh was most similar to native rat tissue in stiffness and breaking load

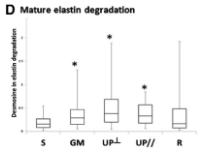
Ulrich D et al., Am J Obstet Gynecol 2015

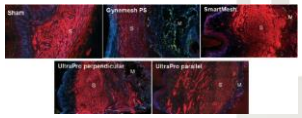
Impact of meshes on the metabolism of vaginal extracellular matrix in rhesus macaque

Collagen degradation in the vagina after mesh implantation



D Mature elastin degradation





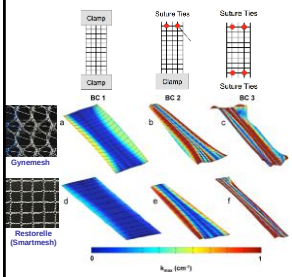
Relative to sham, Gynemesh PS had a negative impact on the metabolism of both collagen and elastin, favoring catabolic reactions, whereas UltraPro induced an increase only in elastin degradation

Lighter, more porous, and less stiff meshes had less of a negative impact

Liang R et al., Am J Obstet Gynecol 2015

Other structural properties (i.e. stress–strain behavior, pore size, pore geometry) are also very important to caracterize new meshes

(Moalli P, IUGA 2013; Feola A et al, 2014)



Hypothesis that regional increases in the concentration of mesh potentially enhance the host's foreign body response, leading to exposure

At a loading force of 10N, Restorelle had significantly lower deformation, both at BC 1 and BC 3 compared to Gynemesh

Barone R et al., J Biomechanics 2015

Clinical data using lighter mesh

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

- ✓ 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

Durability and complications of an ultra lightweight transvaginal mesh in the treatment of pelvic organ prolapse

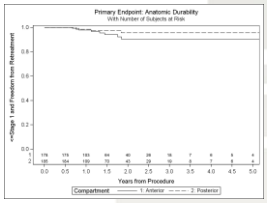
IUGA Poster 2012

R. M. Alinsod[1], M. P. Patel[2], T. B. Erickson[3]
1 South Coast Urogynecology, Laguna Beach, CA, 2 Carolina Urology Partners, Charlotte, NC, 3 Rosemark WomenCare Specialists, Idaho Falls, ID.

- Multicenter retrospective chart review (3 US sites)
- POP stage 3-4 in 58.6%
- 179 anterior Restorelle (Smartmesh)
- Mean f/u 18 months (6 months to 5 years)
- 95.5% anatomical success (Ba <-1 with no retreatment)

Safety:
- 4 exposures (**2.2%**)
- 1 de novo dyspareunia only

Conclusions:
Ultra lightweight transvaginal mesh appears to be durable with low rates of mesh related complications



A pilot study evaluating vaginal mesh palpability and de-novo dyspareunia after trans-vaginal mesh placement

AUGS Poster 2012

J. Tatalovich[1], B. Jamagin[1], E. Campian[1], C. McCoy[2]
1 Ctr. for Pelvic Hlth., Franklin, TN, 2 Medstar Franklin Square Hosp., Baltimore, MD, 3 Central Missouri Women's Hlth.care, Marshall, MO.

- Prospective multicenter study
- 12 anterior Restorelle (Smartmesh)
- f/u 3 months
- Assessment of vaginal palpability of the mesh:
  - blinded examiner
  - 3 anatomical locations both pre and post-op
  - 4 point scale: 0=no, 1= mild, 2=moderate, 3=severe palpability

Location	Palpability	Baseline N=12	3 Months N=12
Anterior–inside hymenal ring	0–None	12 (100.0%)	12 (100.0%)
Anterior–4 cm from the introitus at midline	0–None	12 (100.0%)	11 (91.7%)
	1–Mild	0 (0.0%)	1 (8.3%)
Anterior–apex	0–None	12 (100.0%)	11 (91.7%)
	1–Mild	0 (0.0%)	1 (8.3%)

- No mesh had a moderate to severe vaginal palpability score

EARLY COMPLICATIONS OF AN ULTRA LIGHT WEIGHT TRANSVAGINAL MESH

P Ferry, P Bertherat, H Fernandez,
P Debodinance, R de Tayrac

IUGA e-Poster 2017

- Retrospective multicenter study (4 French centers)
- 74 consecutive anterior Restorelle (incl learning curve)
- f/u 5.5 (2-18) months

- 5 complications Dindo III (6%) / 0% grade IV/V:

  - 2 ureteral kinking (1 arm section vaginally / 1 ureteral reimplantation)
  - 2 haematomas (1 surgical drainage / 1 embolization)
  - 1 reoperated mesh exposure (1.4%)

→ **Very low rate of mesh exposure**
→ Importance of initial training
→ Routine cystoscopy

Clinical data using lighter mesh
(Single incision meshes)

Authors Year	n	Mesh	Weight (g/m²)	Exposure rate	Pain Dyspareunia	Anatomical success
Vu 2012	115	Uphold	41	2.6%	1%	96%
Moore 2012	60	Elevate	25	0%	/	92%
Rapp 2014	42	Elevate	25	5%	3%	90%
Su 2014	100	Elevate	25	3%	/	98%
Lo 2015	65	Elevate	25	0%	/	97%
Stanford 2015	142	Elevate	25	4.9%	/	94%
Huang 2015	210	Elevate	25	1.9%	6%	95%
Rogowski 2015	62	Elevate	25	0%	11%	90%
Letouzey 2015	118	Uphold	41	3.4%	8%	93%
Altman 2016	207	Uphold Lite	26	1.4%	2.4%	94%
Total	**1121**			**2.2%**	**5.2%**	**94.1%**

Uphold™ LITE Vaginal Support System

ORIGINAL ARTICLE

Utero-vaginal suspension using bilateral vaginal anterior sacrospinous fixation with mesh: intermediate results of a cohort study

ORIGINAL ARTICLE

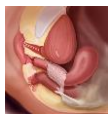
Pelvic organ prolapse repair using the Uphold™ Vaginal Support System: a 1-year multicenter study

Vaginal and laparoscopic mesh hysteropexy for uterovaginal prolapse: a parallel cohort study

Robert E. Gutman, MD; Charles R. Rardin, MD; Eric R. Sokol, MD; Catherine Matthews, MD; Amy J. Park, MD; Cheryl B. Iglesia, MD; Roxana Geoffrion, MD; Andrew I. Sokol, MD; Mickey Karram, MD; Geoffrey W. Cundiff, MD; Joan L. Blomquist, MD; Matthew D. Barber, MD, MHS

Clinical Data - Results

Author Year	Mesh	N	Mean f.u. (month)	Objective success	Subjective success	Severe hemorraghe	Severe pain	Urinary retention	Vaginal mesh exposure
Letouzey 2015	Uphold	118	23	93%	96%	0.8%	0.9%	4.3%	2.7%
Altman 2016	Uphold Lite	207	12	94%	91%	0.5%	0.9%	5.7%	1.4%



Vaginal and laparoscopic mesh hysteropexy for uterovaginal prolapse: a parallel cohort study

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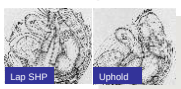


- Objective: to compare 1-year efficacy and safety of laparoscopic sacral hysteropexy vs vaginal mesh hysteropexy

- Methods:
  - Multicenter, prospective parallel cohort study (8 institutions)
  - Women ages 35 to 80 years who desired uterine conservation
  - Stage 2 to 4 symptomatic anterior/apical uterovaginal prolapse
  - Exclusion: cervical elongation, prior mesh repair, cervical dysplasia, chronic pelvic pain, uterine abnormalities, and abnormal bleeding
  - Cure was defined as no prolapse beyond the hymen and cervix above midvagina (anatomic), no vaginal bulge sensation (symptomatic), and no reoperations
  - Power calculation: 72 subjects/group were required to detect 94% vs 75% cure (80% power, 15% dropout)
  - Intention-to-treat analysis adjusting for baseline difference

- Results:
  - 74 laparoscopic SHP vs 76 Uphold/Uphold Lite procedures (2011-2014)
  - Laparoscopic patients were younger, had lower parity, were more likely premenopausal, and had more severe prolapse
  - Laparoscopic procedures were longer (total op time 239 vs 112 min, p<.0001)
  - There were no differences in blood loss, complications, and hospital stay
  - One-year outcomes (available 83% laparoscopic and 80% vaginal hysteropexy patients) revealed no differences in:
    - anatomic (77 vs 80%; adjusted OR 0.48; p=.20)
    - symptomatic (90 vs 95%; adjusted OR 0.40; p=.22)
    - or composite (72 vs 74%; adjusted OR, 0.58; p=.27) cure
  - Mesh exposures occurred in 2.7% laparoscopic vs 6.6% vaginal hysteropexy (p=.44)
  - A total of 95% of each group were very much better or much better
  - Pelvic floor symptom and sexual function scores improved for both groups with no difference between groups

- Conclusion: Laparoscopic sacral hysteropexy and vaginal mesh hysteropexy had similar 1-year cure rates and high satisfaction

Conclusion

✓ Consistent level 1 data demonstrates improved anatomical and subjective outcomes for polypropylene mesh as compared to anterior colporrhaphy (Grade A)

✓ Mesh related complication has to be explained to the patient and taken into account in a case by case decision (extrusion rate 11.5% with 7.0% requiring surgical correction with 2nd mesh generation)

✓ However, mesh related complication is decreasing in the same time of the use of lighter mesh (exposure 2.2%, pain/dyspareunia 5.2%)

… while anatomical and functional results seem comparable

✓ Ultra-light mesh is a promising option (exposure 0-2%, very low rate of dyspareunia), but more clinical data is needed

When using light meshes Vaginal Support System?

1. INDICATIONS	✓ **Primary stage 3-4 anterior/apical POP** ✓ **Recurrence after anterior repair or lap. SCP**
2. 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** ✓ **Respect strict aseptia** ✓ **Perform a deep incision**

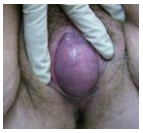
WORKSHOP 11
Progress and controversies in vaginal prolapse surgery

CASE STUDY 3

R de TAYRAC, MD, PhD
Obs/Gyne Dept, CHU Caremeau, Nîmes, France

Mrs U., 74 y.o.

- ✓ 4 vaginal deliveries
- ✓ One previous abdominal sacrocolpopexy 20 years ago
- ✓ Bother by a genital prolapse from 5 years
- ✓ Sexualy active – no dyspareunia
- ✓ OAB, Voiding difficulties



- ✓ GH 6 cm
- ✓ Simplified POP-Q : POP stage 3
  - ✓ Ba : +4 cm
  - ✓ C : 0 cm
  - ✓ Bp : -1 cm
- ✓ No occult SUI

- ✓ Normal cervical sample / normal pelvic US
- ✓ Previous failure physiotherapy and pessary
- ✓ Urodynamic study: Qmax 12 ml/s, PVR 100 ml, Bladder capacity 640 ml
  No DO, PCUM 27 cmH2O, No USI

Question 1.

What are the arguments in favor of the implantation of a mesh in this patient?

1. Age 74 y.o.
2. Previous abdominal sacrocolpopexy
3. OAB
4. POP stage 3

Question 1.

What are the arguments in favor of the implantation of a mesh in this patient?

1. Age 74 y.o.
2. Previous abdominal sacrocolpopexy
3. OAB
4. POP stage 3

Question 2.

What are the arguments in favor of an anterior/apical mesh rather that an anterior mesh only?

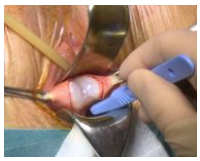
1. Patient sexually active
2. OAB
3. Ba=+4
4. C=0

Question 2.

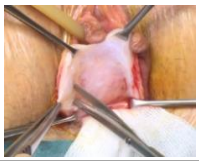
What are the arguments in favor of an anterior/apical mesh rather that an anterior mesh only?

1. Patient sexually active
2. OAB
3. Ba=+4
4. C=0

Surgical steps
Bladder, uterine cervix and paravesical spaces dissection

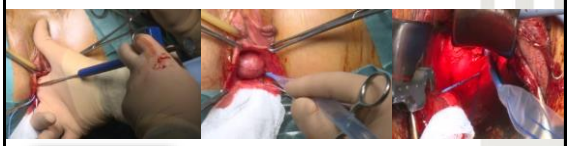


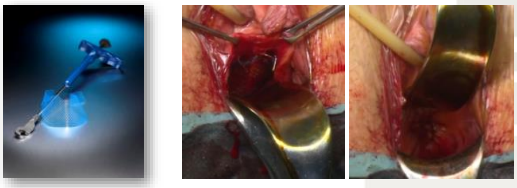
Deep anterior midline incision



Dissection close to the bladder to enter Into the paravesical space

Surgical steps
Bilateral anterior sacrospinous fixation and mesh positionning





Imperial College London

VAGINAL PROLAPSE SURGERY: TO MESH OR NOT TO MESH? THE CURRENT EVIDENCE

Alex Digesu

Alex Digesu

ICS 2017 FLORENCE

Affiliations to disclose†:

ICS Board of Trustee
ICS Educational Committee
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† All financial ties (over the last year) that you may have with any business organisation with respect to the subjects mentioned during your presentation

Funding for speaker to attend:

- [ ] Self-funded
- [ ] Institution (non-industry) funded
- [x] Sponsored by: *International Continence Society*

Background

- Pelvic organ prolapse (POP) is common, affecting as many as 50% of women who have had children.
- 1/9 women will undergo at least one surgery for POP in her lifetime.
- The lifetime risk of undergoing an operation for POP or incontinence by age 80 is 11.1 %.

Background

- The traditional method of repairing vaginal prolapse using native tissue is associated with high rates of recurrence (25-30%) with a re-operation rate at 5 years of 17%.
- It is thought that transvaginal grafts made of absorbable or permanent mesh or biological material may improve the outcomes of prolapse surgery.

What do we know about mesh?

- Mesh for vaginal prolapse was introduced in the late 1990s early 2000s following the successful use of tapes for continence surgery and mesh for hernia surgery.
- The move to use mesh in women with prolapse occurred in the absence of randomized controlled trials.
- The first trials were not published until 2001.
- No specific training was required and the use of mesh was not regulated/monitored until adverse events began to be reported.

FDA

- In 2008 and 2011, the Food and Drug Administration (FDA) released safety communications stating that complications associated with transvaginal mesh use are not rare and that it does not conclusively improve clinical outcomes.
- The FDA has reclassified mesh from class II, which generally includes moderate-risk devices, to class III, which generally includes high-risk devices.
- Subsequent negative publicity and medical litigations resulted in a sharp decline in transvaginal mesh use.

Scientific Committee on Emerging and Newly Identified Health Risks

SCENIHR

Opinion on

The safety of surgical meshes used in urogynecological surgery

- The Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) in June 2015 released an opinion stating that:

"Based on the available scientific evidence, due to increased risks associated with TVM for POP repair, this should only be used when other surgical procedures have failed."

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Imperial College Healthcare NHS Trust

Cochrane Library

2016

Cochrane Database of Systematic Reviews

Transvaginal mesh or grafts compared with native tissue repair for vaginal prolapse (Review)

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

Imperial College London

Imperial College Healthcare NHS Trust

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 parallel-group, multicentre, RCTS:
  - Native tissue repair alone vs standard repair augmented with synthetic mesh (**mesh trial**)
  - Native tissue repair alone vs standard repair augmented with biological graft (**graft trial**)

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	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	83% (283/342)	82% (276/337)	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	0·25 (-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

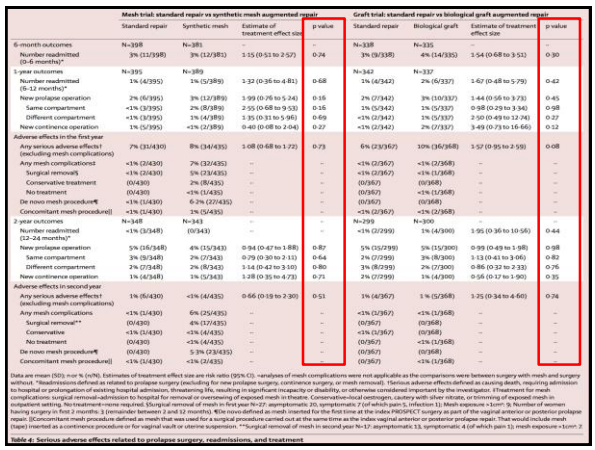
Data are mean (SD); n or % (n/N). Estimates of treatment effect size are mean (95% CI). For all negative continuous outcomes eg, POP-SS (Pelvic Organ Prolapse Symptom Score): a positive effect size favours standard. For all positive continuous outcomes eg, EQ-5D-3L (European Quality of Life-5 Dimensions 3 level): a positive effect size favours synthetic or biological. For all negative dichotomous outcomes: an effect size more than 1 favours standard. For all positive dichotomous outcomes: an effect size more than 1 favours synthetic or biological. SCD=something coming down. QoL=quality of life. ICI= International Consultation on Incontinence. *Symptomatic defined as the number of women with POP-SS >0. †Quality of life due to prolapse symptoms measured as the overall interference of prolapse symptoms with everyday life using a visual analogue scale; scores range from 0 (not at all) to 10 (a great deal). ‡Severe urinary incontinence defined as a score of 13–21 on the International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form questionnaire. §Faecal incontinence of solid or liquid stool (any) defined as occasionally or more. ¶Severe dyspareunia defined as answering "a lot" to the question: "Do you have pain when you have sexual intercourse?"

Table 2: Clinical symptoms and quality of life outcomes

	Mesh trial: standard repair vs synthetic mesh augmented repair				Graft trial: standard repair vs biological graft augmented repair			
	Standard repair (n=381)	Synthetic mesh (n=374)	Estimate of treatment effect size	p value	Standard repair (n=319)	Biological graft (n=319)	Estimate of treatment effect size	p value
POP-Q (cm from hymen)								
Ba (anterior edge)	-1·3 (1·6); 323	-1·3 (1·6); 327	0·06 (-0·17 to 0·29)	0·62	-1·3 (1·7); 293	-1·2 (1·7); 293	0·12 (-0·1 to 0·4)	0·34
C (cervix/vault)	-6·0 (2·1); 318	-6·0 (2·3); 321	-0·03 (-0·36 to 0·31)	0·88	-5·8 (1·9); 292	-5·7 (2·1); 292	0·15 (-0·2 to 0·5)	0·37
Bp (posterior edge)	-2·0 (1·2); 322	-2·1 (1·1); 326	-0·03 (-0·21 to 0·15)	0·74	-2·1 (1·2); 299	-2·0 (1·2); 290	0·13 (-0·1 to 0·3)	0·20
Total vaginal length	8·1 (1·2); 320	8·2 (1·3); 318	0·12 (-0·07 to 0·30)	0·21	7·8 (1·2); 291	7·8 (1·2); 286	0·07 (-0·1 to 0·3)	0·50
Overall POP-Q stage*								
0	16% (56/341)	14% (48/339)	1·11 (0·83 to 1·47)	0·49	17% (51/305)	14% (42/299)	1·26 (0·93 to 1·71)	0·13
1	32% (108/341)	33% (113/339)	..	..	31% (96/305)	28% (85/299)	..	..
2	45% (153/341)	47% (158/339)	..	..	44% (135/305)	48% (144/299)	..	..
3	6% (22/341)	6% (19/339)	..	..	7% (21/305)	8% (25/299)	..	..
4	<1% (2/341)	<1% (1/339)	..	..	<1% (2/305)	1% (3/299)	..	..
2b, 3, or 4†	14% (47/338)	16% (54/336)	1·12 (0·79 to 1·60)	0·52	16% (47/303)	18% (54/298)	1·14 (0·80 to 1·62)	0·47

Data are mean (SD); n or % (n/N). Estimates of treatment effect size are mean (95% CI). POP-Q=Pelvic Organ Prolapse Quantification system. Ba=the most dependent part of the anterior vaginal wall. C=the most dependent part of the cervix or the vaginal cuff if patient has no cervix. Bp=the most dependent part of the posterior vaginal wall.. ..=no available data here. *Calculated from POP-Q, or stage as reported by clinicians when POP-Q not done. †Objective prolapse: stage 2b, 3, or 4, defined as leading edge beyond the hymen (>0 cm) when POP-Q data available.

Table 3: Objective measures of prolapse at 1-year clinical review



	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	–	–
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)	0·15	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% (1/368)	–	–
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 10·58)	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)	–	–

Data are mean (SD) n or % (n/N). Estimates of treatment effect size are risk ratios (95% CI). –analyses of mesh complications were not applicable as the comparisons were between surgery with mesh and surgery without. *Readmissions defined as related to prolapse surgery (excluding for new prolapse surgery, continence surgery, or mesh removal). †Serious adverse effects defined as causing death, requiring admission to hospital or prolongation of existing hospital admission, threatening life, resulting in significant incapacity or disability, or otherwise considered important by the investigator. ‡Treatment for mesh complications: surgical removal=admission to hospital for removal or overrowing of exposed mesh in theatre. Conservative=local oestrogen, cautery with silver nitrate, or trimming of exposed mesh in outpatient setting. No treatment=none required. §Surgical removal of mesh in first year N=27: asymptomatic 20, symptomatic 7 (of which pain 5, infection 1); Mesh exposure >1cm²: 9; Number of women having surgery in first 2 months: 3 (remainder between 2 and 12 months). ¶De novo defined as mesh inserted for the first time at the index PROSPECT surgery as part of the vaginal anterior or posterior prolapse repair. ‖Concomitant mesh procedure defined as mesh that was used for a surgical procedure carried out at the same time as the index vaginal anterior or posterior prolapse repair. That would include mesh (tape) inserted as a continence procedure or for vaginal vault or uterine suspension. **Surgical removal of mesh in second year N=17: asymptomatic 13, symptomatic 4 (of which pain 1); mesh exposure >1cm²: 2

Table 4: Serious adverse effects related to prolapse surgery, readmissions, and treatment

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)**

- **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 1:10 women had a mesh complication.**

www.thelancet.com **Vol 389 January 28, 2017**

Royal College of Obstetricians and Gynaecologists

BSUG British Society of Urogynaecology

- DO not support the first-line use of transvaginal mesh
- Women should be fully informed of the potential complications.

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THE SOCIETY OF OBSTETRICIANS AND GYNAECOLOGISTS OF CANADA

- Women considering prolapse surgery should be counselled about the potentially serious adverse sequelae, including mesh exposure, pain, and dyspareunia.

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ACOG

THE AMERICAN CONGRESS OF OBSTETRICIANS AND GYNECOLOGISTS

- Vaginal mesh should be reserved for high-risk individuals where the benefit might justify the risk.

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ACOG THE AMERICAN CONGRESS OF OBSTETRICIANS AND GYNECOLOGISTS

THE SOCIETY OF OBSTETRICIANS AND GYNAECOLOGISTS OF CANADA

BSUG British Society of Urogynaecology

Royal College of Obstetricians and Gynaecologists

- All the guideline groups now recommend **training** in the use of mesh prior to its use.

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Imperial College Healthcare NHS Trust

THE TAKE-HOME MESSAGE

Anterior compartment

- Standard native tissue-based repairs in the anterior compartment have long been thought to be associated with high anatomical recurrence rates and the currently available RCTs support this thinking.
- However, subjective improvement in pelvic pressure and bulging and quality of life indices are similarly improved in both standard and mesh-augmented repairs.

Posterior compartment

- No RCTs are available to compare standard and mesh-augmented repairs in the posterior compartment

Synthetic permanent mesh

- Transvaginal permanent mesh compared to native tissue repair is associated with:
  - **Lower rates of awareness of POP**
  - **Prolapse on examination**

BUT

  - **Higher rates of repeat surgery for:**
  - **POP**
  - **SUI**
  - **Mesh exposure**
  - **Bladder injury at surgery**
  - **De novo stress urinary incontinence**

Synthetic permanent mesh

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

Synthetic lightweight transvaginal permanent meshes

- In 2011, many transvaginal permanent meshes were voluntarily withdrawn from the market, and the newer, lightweight transvaginal permanent meshes still available have not been evaluated within a RCT.
- Therefore, these newer transvaginal meshes should be utilised under the discretion of the ethics committee.

Absorbable & biological mesh

- Limited evidence suggests that absorbable mesh may reduce rates of recurrent POP on examination compared to native tissue repair.
- Insufficient evidence on absorbable mesh for other outcomes.
- Insufficient evidence to draw any conclusions regarding biological grafts compared to native tissue repair.

- Negative publicity and medicolegal issues have caused a significant decrease in mesh usage, especially in the USA and many western countries.
- There is a real need to establish appropriate criteria for TVM usage.
- For recurrent prolapse, success rates with TVM are better than with NT repair but the total re-operation rates are similar when mesh complication-related surgeries are taken into account.

- From the evidence to date, even in women with recurrent POP, it is not possible to conclude that the benefits of TVM outweigh the risks.
- The option to use TVM is important for a pelvic surgeon to have after careful counselling of patients with recurrent prolapse, carefully exploring patient expectations as the overall patient benefit is unclear.
- Further prospective studies using validated questionnaires, especially in the subgroup of women with recurrent prolapse, will be the way forward in determining the risks and benefits of TVM.

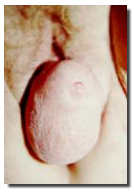
- Women and their surgeons need to discuss these benefits and harms at the time of considering surgery.
- Our patients deserve better studies and, in the absence of evidence, better advice.

ICS WORKSHOP 11
Progress and controversies in vaginal prolapse surgery

CASE STUDY 4

MEDIZINISCHE UNIVERSITÄT WIEN HUG Hôpitaux Universitaires Genève

Mrs C., 62 y.o.



- nulliparous
- No prior surgery
- No regular gynecologic follow-up
- Prolapse symptoms for many years (« heaviness », « difficulties to sit »)
- Not sexually active
- No LUTS

- ✓ GH 7 cm
- ✓ Simplified POP-Q : POP stage 4
  - ✓ Ba : +2 cm
  - ✓ C : +5 cm
  - ✓ Bp : +4 cm
- ✓ No occult SUI

- Endometrial and cervical sample repeatedly AGUS NOS
- Pessary trial unsuccessful (Gelhorn/Donut led to erosions)

Question

What surgical technique would you have chosen?

1. Vaginal hysterectomy and McCall culdoplasty or sacrospinous fixation
2. Uterus conserving treatment with site specific repair
3. Transvaginal Mesh surgery
4. Laparoscopic repair or other