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

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<td>Nikolaus Veit-Rubin</td>
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<td>Heinz Kölbl</td>
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<td>Case study: Native tissue repair</td>
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<td>Renaud De Tayrac</td>
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<td>Vaginal prolapse surgery: To mesh or not to mesh? - Current evidence</td>
<td>Alex Digesu</td>
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<td>12:20</td>
<td>Case study: What to do for primary repair</td>
<td>All</td>
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<td>12:20</td>
<td>12:30</td>
<td>Discussion</td>
<td>All</td>
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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](http://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 In 2011, after the FDA warning, many transvaginal meshes were voluntarily withdrawn from the market under economic and juridical pressure and the debates were increasingly dominated by emotion rather than scientific facts.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 tissue 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 Köbl, 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 Reading before Workshop Attendance


Suggested Reading

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.

References

Smith FJ et al, Obstet Gynecol 2010
Wu JM et al, Am J Obstet Gynecol 2011
Recurrence in Native Tissue repair

- high recurrence rates, \( \text{m} \)

\[ \text{Yes, BUT...} \]

- 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, Neurourology Urodyn 2009
Nüessler 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)

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

**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)


1st warning about increased adverse events

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

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)
Mesh Hype Cycle

VISIBILITY

2004
Technology Trigger
2010
Trough of Disillusionment
Plateau of Productivity
Peak of Inflated Expectations
2016

Time

To mesh or not to mesh?

Innovation adaptation curve
depictions of how a technology or application will evolve over time

The Hype Cycle

Iglesia C. et al, OBG Management 2013
Thank you for your attention!
CASE STUDY 1

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?)

Mrs K., 56 y.o.

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

2 months AFTER SURGERY:
- GH: 4 cm
- Simplified POP-Q: POP stage 2
  - Ba: -2 cm
  - C: -2 cm
  - Bp: +1 cm

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?)
Vaginal Prolapse Surgery with Native Tissue Repair

Univ. Prof. Dr. Dr. h.c. Heinz Koelbl
Department of General Gynecology and Gynecological 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

80,000 Interventions for PFR - and Incontinence Surgery per year in Germany

Aims of pelvic floor reconstructive surgery

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

Various forms of Prolapse

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

middle compartment
- abdominal hysterectomy ± sacrocolpopexy
- vaginal hysterectomy ± sacrospinous/ischiozygous fixation
- abdominal or vaginal sacrospinous fixation/sacrohysteropexy

posterior compartment
- posterior repair
- rectopexy
- anal sphincter repair

Surgical options

ANTERIOR
- Anterior colporrhaphy

APICAL
- Anterior colporrhaphy

WITH
- Vaginal Hysterectomy
  - McCall Culdoplasty
  - Uterosacral fixation

WITHOUT
- Vaginal Hysterectomy
  - Sacrospinous fixation (Richter)
  - 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
Anterior repair

- Indication: central anterior defect

<table>
<thead>
<tr>
<th></th>
<th>Mesh</th>
<th>Colporrhaphy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objective cure rate</td>
<td>60.8%</td>
<td>34.5%</td>
</tr>
<tr>
<td>Operation time (min)</td>
<td>35.5</td>
<td>52.6</td>
</tr>
<tr>
<td>Blood loss (ml)</td>
<td>35.4</td>
<td>94.7</td>
</tr>
<tr>
<td>Bladder perforation</td>
<td>3.5%</td>
<td>0.5%</td>
</tr>
<tr>
<td>New SUI</td>
<td>12.3%</td>
<td>6.3%</td>
</tr>
<tr>
<td>Revision for mesh exposure</td>
<td>2%</td>
<td>0</td>
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</table>

389 women: 200 mesh vs 189 traditional colporrhaphy
Anterior Colporrhaphy versus Transvaginal Mesh for Pelvic-Organ Erosion

CONCLUSIONS
As compared with anterior colporrhaphy, use of a standardized, surgeon-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.

Results paravaginal defect repair

<table>
<thead>
<tr>
<th></th>
<th>Cystocele cured</th>
<th>GSI cured</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>(%)</td>
<td>(%)</td>
</tr>
<tr>
<td>Richardson et al.</td>
<td>60</td>
<td>97</td>
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<tr>
<td>Baden &amp; Walker</td>
<td>173</td>
<td>78</td>
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<tr>
<td>Shull &amp; Baden</td>
<td>149</td>
<td>95</td>
</tr>
<tr>
<td>Ball</td>
<td>200</td>
<td>96</td>
</tr>
<tr>
<td>Richardson</td>
<td>800</td>
<td>95</td>
</tr>
<tr>
<td>Shull et al</td>
<td>62</td>
<td>76</td>
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<tr>
<td>Milani et al</td>
<td>109</td>
<td>91</td>
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Defect repair – middle compartment

Vaginal hysterectomy

- Uterosacral Fixation
- McCall Culdoplasty
- Sacrospinous Fixation

- Illococcygeus fixation
- Manchester procedure
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%

Author n Pts follow-up mths Rec. %
Paraiso 243 36 20 8,2
Albrech 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
Koelln 200 60 4 3,2
TOTAL: 1854 47 67 3,2

Sacrospinous fixation of the vagina

Comparaison IRM

Mesures IRM de l’axe vaginal en post-opératoire

Après promontofixation

Après Richter

Axé physiologique

SZE et al., Int Urogynecol J 2001

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

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

Matthew D. Bohan, MD, MPH, Linda Babutke, MD, Katharine K. Bagley, MD, Holly F. Borer, MD, MD, Ingrid Beier-Hogan, MD, Alon R. C. Woerner, MD, Steven A. Messerle, MD, Emry L. Luker, MD, Peggy Pernymes, MD, Joseph Schettler, MD, John G. Nissen, MD, Jaime Batista-Parras, PhD, Patricia J. Savarese, MD, Mirella Salata-Miller, MD, Jacqueline L. Zuckier, MD, Lauren Mann, MD, Marc A. Gutman, PhD, Susan H. Middle, MD, for the EuroCOHoMENiM, National Institutes of Child Health and Human Development: Nerve Trunk Disorders Network

CONCLUSIONS AND RECOMMENDATIONS
Two years after surgical repair for prolapse and stress urinary incontinence, neither US or SUT was significantly superior to the other for anatomical, functional, or adverse events outcomes. Perioperative BPMFT did not improve urinary symptoms at 6 months or prolapse outcomes at 2 years.

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
Tipton J et al, Obstet Gynecol Br Commonw 1970
Paz-Levy et al, Int Urogyn J 2017

Posterior colporrhaphy

<table>
<thead>
<tr>
<th>Author</th>
<th>Follow-up</th>
<th>Obstructed</th>
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<tr>
<td>Mellgren</td>
<td>postop.</td>
<td>48%</td>
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<tr>
<td>Infantino</td>
<td>36 Mo</td>
<td>25%</td>
<td></td>
</tr>
<tr>
<td>Cundiff</td>
<td>12 Mo</td>
<td>8%</td>
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Conclusion

- Scarcity of studies reporting functional outcomes
- Overall high rate of efficacy for native tissue repair procedures
- Few complications, 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

Perspectives in Urogynecology

➢ Genomics
➢ Proteomics
➢ Biomarker

RISK GROUP ASSESSMENT

IN VITRO

DNA – Fluorescence with Propriumiodide – day 8

Max University Hospital, Department of Obstetrics & Gynecology, 05105 Reutlingen, Germany. skala@vs-reut.de

IN VIVO

Skala et al.: Regen Med 2010

Thank you!
CASE STUDY 2

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

Identification and exposure of the sacrospinous ligament

Identification and exposure of the sacrospinous ligament

Suture placement at the sacrospinous ligament

Suture placement at the level of the cervix

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

R de TAYRAC, MD, PhD
Ob/Gyné Dept, CHU Caremeau, Nîmes, France

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

Disclosure

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

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)
✓ Ultra-light mesh < 20-25 g/m²


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

Marked Inflammatory response

Evolution of mesh mass density over years

- Pelviflex
- Genemesh +m pre implant
- Gynemesh
- Prolene Soft
- Genemesh +m Post-implant
- Ultrapro
- IntePro Lite
- Novasilk
- Restorelle
Basic science rational behind ultra-light meshes


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

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 characterize new meshes

(Mouli P, IUGA 2013; Festa A et al, 2014)

Clinical data using lighter mesh

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

Restorelle® Single incision mesh

Prospective multicenter study
• 12 anterior Restorelle (Smartmesh)
• 6/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

AUGS Poster 2013

Restorelle® Single incision mesh

Prospective multicenter study
• 12 anterior Restorelle (Smartmesh)
• 6/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

AUGS Poster 2013

• No mesh had a moderate to severe vaginal palpability score
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)

<table>
<thead>
<tr>
<th>Author Year</th>
<th>n</th>
<th>Mesh</th>
<th>Weight (g/m²)</th>
<th>Exposure rate</th>
<th>Pain</th>
<th>Urinary retention</th>
<th>Vaginal mesh exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vu 2012</td>
<td>115</td>
<td>Uphold</td>
<td>41</td>
<td>2.6%</td>
<td>1%</td>
<td>0%</td>
<td>2.7%</td>
</tr>
<tr>
<td>Moore 2012</td>
<td>60</td>
<td>Elevate</td>
<td>25</td>
<td>0%</td>
<td>/</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>Rapp 2014</td>
<td>42</td>
<td>Elevate</td>
<td>25</td>
<td>5%</td>
<td>3%</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>Su 2014</td>
<td>108</td>
<td>Elevate</td>
<td>25</td>
<td>3%</td>
<td>/</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>Le 2015</td>
<td>65</td>
<td>Elevate</td>
<td>25</td>
<td>0%</td>
<td>/</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>Stanford 2015</td>
<td>142</td>
<td>Elevate</td>
<td>25</td>
<td>4.9%</td>
<td>/</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>Hsung 2015</td>
<td>210</td>
<td>Elevate</td>
<td>15</td>
<td>1.9%</td>
<td>6%</td>
<td>0%</td>
<td>9%</td>
</tr>
<tr>
<td>Rogowski 2015</td>
<td>62</td>
<td>Elevate</td>
<td>25</td>
<td>0.0%</td>
<td>11%</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>Letouzey 2015</td>
<td>118</td>
<td>Uphold</td>
<td>41</td>
<td>3.4%</td>
<td>8%</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>Allen 2016</td>
<td>207</td>
<td>Uphold Lite</td>
<td>26</td>
<td>1.4%</td>
<td>2.4%</td>
<td>/</td>
<td>94%</td>
</tr>
<tr>
<td>Total</td>
<td>1121</td>
<td></td>
<td></td>
<td>2.2%</td>
<td>5.2%</td>
<td>4%</td>
<td>94.1%</td>
</tr>
</tbody>
</table>

• 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=0.20)
    • symptomatic (92 vs 95%, adjusted OR 0.48, p=0.22)
    • or composite (72 vs 74%, adjusted OR, 0.58, p=0.27) cure
  - Mesh exposures occurred in 2.7% laparoscopic vs 6.6% vaginal hysteropexy (p=0.44)
  - 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

<table>
<thead>
<tr>
<th>Vaginal Support System?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. INDICATIONS</strong></td>
</tr>
<tr>
<td>✓ Primary stage 3-4 anterior/apical POP</td>
</tr>
<tr>
<td>✓ Recurrence after anterior repair or lap. SCP</td>
</tr>
<tr>
<td><strong>2. CONTRA-INDICATIONS</strong></td>
</tr>
<tr>
<td>✓ Women before 50 or after 80 years-old</td>
</tr>
<tr>
<td>✓ Tobacco use</td>
</tr>
<tr>
<td>✓ Previous post-operative infection / radiotherapy</td>
</tr>
<tr>
<td>✓ Non-equilibrated diabetes / long-term steroid use / immunodepression / chronic hepatitis with ascitis</td>
</tr>
<tr>
<td>✓ Intra-operative bladder or rectal injury</td>
</tr>
<tr>
<td><strong>3. PREOP PATIENT INFORMATION</strong></td>
</tr>
<tr>
<td>Give a pre-operative honest patient's information on: Risk / Benefit</td>
</tr>
<tr>
<td><strong>4. RESPECT SURGICAL RULES</strong></td>
</tr>
<tr>
<td>✓ Have enough surgical training and experience</td>
</tr>
<tr>
<td>✓ Respect strict asepsia</td>
</tr>
<tr>
<td>✓ Perform a deep incision</td>
</tr>
</tbody>
</table>
CASE STUDY 3

Mrs U., 74 y.o.
- 4 vaginal deliveries
- One previous abdominal sacrocolpopexy 20 years ago
- Bother by a genital prolapse from 5 years
- Sexually 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
  - Urodynaminc 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 2.
What are the arguments in favor of an anterior/apical mesh rather than 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 positioning
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%.

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.

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

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

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**Cochrane Library**

**2016**

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

- 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)

---

**Mesh trial standard repair vs synthetic mesh augmented repair**

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Local pain (n=120)</th>
<th>Pain 1 week (n=120)</th>
<th>Pain 2 weeks (n=120)</th>
<th>Time to return to normal activities (n=120)</th>
<th>Total length (n=120)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard repair</td>
<td>1 (1-2)</td>
<td>1 (1-2)</td>
<td>1 (1-2)</td>
<td>12 (10-15)</td>
<td>134 (120-144)</td>
</tr>
<tr>
<td>Synthetic mesh</td>
<td>1 (1-2)</td>
<td>1 (1-2)</td>
<td>1 (1-2)</td>
<td>12 (10-15)</td>
<td>134 (120-144)</td>
</tr>
</tbody>
</table>

**Graft trial standard repair vs biological graft augmented repair**

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Local pain (n=120)</th>
<th>Pain 1 week (n=120)</th>
<th>Pain 2 weeks (n=120)</th>
<th>Time to return to normal activities (n=120)</th>
<th>Total length (n=120)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard repair</td>
<td>1 (1-2)</td>
<td>1 (1-2)</td>
<td>1 (1-2)</td>
<td>12 (10-15)</td>
<td>134 (120-144)</td>
</tr>
<tr>
<td>Biological graft</td>
<td>1 (1-2)</td>
<td>1 (1-2)</td>
<td>1 (1-2)</td>
<td>12 (10-15)</td>
<td>134 (120-144)</td>
</tr>
</tbody>
</table>

---

**Notes:**

- Data are from PROSPERCT, a randomised controlled trial comparing standard repair with synthetic mesh and standard repair with biological graft.
- The primary outcome was time to return to normal activities.
- Secondary outcomes included pain and total length of operation.
- The study was conducted in 10 centres in the UK and Canada.
- The results showed no significant difference between the two groups in terms of pain or time to return to normal activities.
- Further research is needed to confirm these findings and to determine the long-term effectiveness of these interventions.
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.

• DO not support the first-line use of transvaginal mesh

• Women should be fully informed of the potential complications.

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

• All the guideline groups now recommend training in the use of mesh prior to its use.
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
  - Higher rates of repeat surgery for:
    - POP
    - SUI
    - Mesh exposure
    - Bladder injury at surgery
  - De novo stress urinary incontinence

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.

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.
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.

Summary

- 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.
**CASE STUDY 4**

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